ZOETIS EQUINE PRODUCTS

ANTI-INFLAMMATORIES

DEPO-MEDROL® (methylprednisolone acetate) Injectable ................................................. 4
DOMOSO® SOLUTION (dimethyl sulfoxide) ................................................................. 4
HYLARTIN® V (sodium hyaluronate) Injection ............................................................... 5
PREDEF® 2X (isoflupredone acetate) Sterile Aqueous Suspension ............................... 5

ANTI-INFECTIVES

AMIGLYDE®-V (amikacin sulfate) .................................................................................. 6
EXCEDE® Sterile Suspension (ceftiofur crystalline free acid) ........................................ 6
NAXCEL® Sterile Powder (ceftiofur sodium) ................................................................. 7
TUCOPRIM® (trimethoprim and sulfadiazine powder) .................................................... 7

ANTISEPTICS

NOLVASAN® Solution (chlorhexidine diacetate) ............................................................ 8
NOLVASAN® S (chlorhexidine diacetate) ..................................................................... 8
NOLVASAN® Skin and Wound Cleanser (chlorhexidine) .............................................. 8
NOLVASAN® Surgical Scrub (chlorhexidine) ................................................................. 8

VACCINES

ARVAC® Equine Arteritis Virus Vaccine ........................................................................... 9
EQUILOID INNOVATOR® Encephalomyelitis Vaccine-Tetanus Toxoid .............................. 9
EQUIVAC INNOVATOR® EHV-1/4 Rhinopneumonitis Vaccine ...................................... 9
FLUVAC INNOVATOR® Equine Influenza Vaccine .......................................................... 10
FLUVAC INNOVATOR® EHV-4/1 Rhinopneumonitis-Equine Influenza Vaccine ............ 10
FLUVAC INNOVATOR® 4 Encephalomyelitis-Influenza Vaccine-Tetanus Toxoid ........... 11
FLUVAC INNOVATOR® 5 Encephalomyelitis-Rhinopneumonitis Influenza Vaccine-Tetanus Toxoid .......................................................... 11
FLUVAC INNOVATOR® 6 Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine-Tetanus Toxoid .......................................................... 12
**PARASITICIDES & INSECTICIDES**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTHELCIDE® EQ PASTE (oxibendazole)</td>
<td>22</td>
</tr>
<tr>
<td>QUEST® GEL (moxidectin)</td>
<td>22</td>
</tr>
<tr>
<td>QUEST® PLUS GEL (moxidectin/praziquantel)</td>
<td>23</td>
</tr>
<tr>
<td>SOLITUDE® IGR Feed-Through Pellet (2.12% cyromazine)</td>
<td>23</td>
</tr>
<tr>
<td>STRONGID® PASTE (pyrantel pamoate)</td>
<td>24</td>
</tr>
<tr>
<td>STRONGID® C/C2X Equine Anthelmintic (pyrantel tartrate)</td>
<td>24</td>
</tr>
<tr>
<td>STRONGID® T Suspension (pyrantel pamoate)</td>
<td>25</td>
</tr>
</tbody>
</table>

**SEDATIVES, ANESTHETICS & ANALGESICS**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARBOCAINE®-V Sterile Aqueous Solution (mepivacaine hydrochloride)</td>
<td>27</td>
</tr>
<tr>
<td>DORMOSEDAN® (detomidine hydrochloride)</td>
<td>27</td>
</tr>
<tr>
<td>DORMOSEDAN GEL® (detomidine hydrochloride)</td>
<td>28</td>
</tr>
<tr>
<td>FLUNIXAMINE® Injectable Solution (flunixin meglumine)</td>
<td>28</td>
</tr>
<tr>
<td>KETOFEN® Sterile Solution (ketoprofen)</td>
<td>29</td>
</tr>
<tr>
<td>TORBUGESIC® (butorphanol tartrate)</td>
<td>29</td>
</tr>
</tbody>
</table>
# ZOETIS EQUINE PRODUCTS

## SUPPLEMENTS
- CLOVITE<sup>®</sup> Conditioner ................................................................. 30
- LIXOTINIC<sup>®</sup> Liquid ................................................................. 30

## REPRODUCTIVE
- LUTALYSE<sup>®</sup> INJECTION (dinoprost injection) ............................................. 31

## OTHER
- KOPERTOX<sup>®</sup> ................................................................. 32

## SERVICES
- PEOPLEFIRST™ ................................................................. 33

## PRESCRIBING INFORMATION
- AMIGLYDE<sup>®</sup>-V (amikacin sulfate) ....................................................... 35
- CARBOCAINE<sup>®</sup>-V Sterile Aqueous Solution (mepivacaine hydrochloride) .......... 36
- DEPO-MEDROL<sup>®</sup> Injectable (methylprednisolone acetate) ......................... 37
- DOMOSO<sup>®</sup> SOLUTION (dimethyl sulfoxide) ........................................... 38
- DORMOSEDAN<sup>®</sup> (detomidine hydrochloride) ........................................... 40
- DORMOSEDAN GEL<sup>®</sup> (detomidine hydrochloride) ................................... 41
- EXCEDE<sup>®</sup> Sterile Suspension (ceftiofur crystalline free acid) ....................... 43
- FLUNIXAMINE<sup>®</sup> Injectable Solution (flunixin meglumine) ....................... 44
- HYLARTIN<sup>®</sup> V Injection (sodium hyaluronate) ........................................ 45
- KETOFEN<sup>®</sup> Sterile Solution (ketoprofen) .............................................. 46
- LUTALYSE<sup>®</sup> Injection (dinoprost injection) ........................................... 47
- NAXCEL<sup>®</sup> Sterile Powder (ceftiofur sodium) ......................................... 49
- PREDEF<sup>®</sup> 2X Sterile Aqueous Suspension (isoﬂupredone acetate) ................. 51
- STRONGID<sup>®</sup> T Suspension (pyrantel pamoate) ...................................... 52
- TORBUGESIC<sup>®</sup> (butorphanol tartrate) ................................................ 53
- TUCOPRIM<sup>®</sup> (trimethoprim and sulfadiazine powder) ........................... 54
**DEPO-MEDROL® Injectable**  
(*methylprednisolone acetate*)

**USES:**  
For the treatment of pain and lameness associated with acute localized arthritic conditions and generalized arthritic conditions.

**SUPPLIED:**  
- 20 mg/mL (20 mL vial)  
- 40 mg/mL (5 mL vial)

**KEY FACTS:**  
- Produces a more prolonged anti-inflammatory effect than equimolar hydrocortisone acetate.  
- Provides relief from pain within 12-24 hrs of intrasynovial injection.  
- Duration of pain relief averages 3-4 weeks, in some cases longer.  
- The usual intramuscular dose for horses is 200 mg repeated as necessary.  
- The usual intrasynovial dose for horses is between 40mg and 240 mg with a total body target dose of 100 mg for performance horses.  
- Research updates on withdrawal time at: http://www.rmtcnet.com/withdrawal_agree.asp

**IMPORTANT SAFETY INFORMATION:**  
Do not use DEPO-MEDROL in animals with tuberculosis, peptic ulcer and Cushing’s syndrome. Use with extreme caution in pregnant animals. Watch for evidence of concurrent infection. See full Prescribing Information, attached.

**DOMOSO® Solution**  
(*dimethyl sulfoxide*)

**USES:**  
Administer topically to reduce acute swelling due to trauma. For the treatment of pain relief and inflammation in critical conditions.

**SUPPLIED:**  
- 1 pint bottle  
- 1 gallon bottle

**KEY FACTS:**  
- Medical grade Dimethyl Sulfoxide.  
- Provides relief of pain and inflammation.  
- Apply liberally 3-4 times per day but do not exceed 100 mL.  
- It may mask certain disease signs such as are seen in fractures, it should not be used directly prior to racing or other physical stress.

**IMPORTANT SAFETY INFORMATION:**  
Avoid contact of DOMOSO SOLUTION with skin and eyes. Use gloves and apply in a well ventilated area. For topical use only. Do not use in conditions of physical stress or activity where this product could mask existing pathology. Use caution when applying other topical drugs, and in conjunction with other pharmaceutical preparations, especially those affecting the cardiovascular and central nervous system. See full Prescribing Information, attached.
**HYLARTIN® V Injection**  
*(sodium hyaluronate)*

**USES:**
Treatment of joint dysfunction due to non-infectious synovitis associated with equine osteoarthritis. For small to medium sized joints (carpal, fetlock) dosage of 2mL is administered. For the treatment of larger joints (hock) dosage is 4 mL.

**SUPPLIED:**
• 2 mL vials containing 20mg of active ingredient

**KEY FACTS:**
• Lubricates the soft tissues of the joint – reducing friction and improving joint activity by replacing natural hyaluronate.
• The highest molecular weight HA approved for equine (up to 6X the weight of low molecular weight competitor Hylovet®).
• Superior viscosity contributes to the maximum possible period of soundness, at least 16 weeks.1
• May be repeated at weekly intervals for a total of three treatments.
• Horses should be given two days stall rest before gradually resuming normal activity.

**IMPORTANT SAFETY INFORMATION:**
Do not administer HYLARTIN V intravascularly. Occasional mild side effects may include heat, transient edema and pain around the treated joint. Do not use in horses intended for human consumption. See full Prescribing Information, attached.

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**PREDEF® 2X Sterile Aqueous Suspension**  
*(isoflupredone acetate)*

**USES:**
Administered by deep intramuscular injection for systematic effect, or into joint cavity, tendon sheath, or bursa for local effect.

**SUPPLIED:**
• 100 mL vial

**KEY FACTS:**
• Treatment was found useful in alleviating the pain and lameness associated with generalized and local arthritic conditions.
• Dosage is 5 to 20 mg repeated as necessary depending on the size of the cavity to be injected.

**IMPORTANT SAFETY INFORMATION:**
Do not use in horses intended for human consumption. When administered during the last trimester of pregnancy, use of oral or injectable corticosteroids may induce parturition and may be associated with birth related complications and birth defects. See full Prescribing Information, attached.

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AMIGLYDE®-V
(*amikacin sulfate*)

**USES:**
Treatment of uterine infections (endometritis, metritis and pyometra) caused by *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

**SUPPLIED:**
• 48 mL vial

**KEY FACTS:**
• Amikacin has been shown to be effective against many aminoglycoside-resistant strains due to its ability to resist degradation by certain aminoglycoside inactivating enzymes.

**IMPORTANT SAFETY INFORMATION:**
Concurrent use of other aminoglycosides should be avoided because of the potential for additive effects. Do not use AMIGLYDE V in horses intended for human consumption. See full Prescribing Information, attached.

EXCEDE® Sterile Suspension
(*ceftiofur crystalline free acid*)

**USES:**
A sustained-release antibiotic used in the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi subspecies zooepidemicus* (*S. zooepidemicus*).

**SUPPLIED:**
• 100 mL vial
• 250 mL vial

**KEY FACTS:**
• First and only licensed antibiotic that offers a full 10-day course of therapy in just 2 treatments.
• One single sustained dose provides therapeutic care for 96 hours.
• The sustained-release nature of the product means less systemic exposure to the antibiotic with comparable efficacy.
• 100% effective against target pathogens.
• FDA Approved for horses.
• Dosage of two intramuscular injections, 96 hours apart, at a dosage of 1.5 mL/100 lb body weight provides 10 days of therapy for optimized compliance.
• A maximum of 20 mL per injection site may be administered.
• Contents should be used within 12 weeks after the first dose is removed.

**IMPORTANT SAFETY INFORMATION:**
People with known hypersensitivity to penicillin or cephalosporins should avoid exposure to EXCEDE. EXCEDE is contraindicated in animals with known allergy to ceftiofur or to the β-lactam group (penicillin and cephalosporins) of antimicrobials. Do not use in horses intended for human consumption. The administration of antimicrobials in horses under conditions of stress may be associated with diarrhea, which may require appropriate veterinary therapy. See full Prescribing Information, attached.
NAXCEL® Sterile Powder
(ceftiofur sodium)

USES:
The treatment of respiratory infections associated with Streptococcus equi subspecies (S. zooepidemicus).

SUPPLIED:
- 1 gram vial
- 4 gram vial

KEY FACTS:
- Administer by intramuscular injection at the dosage of 1 to 2 mg ceftiofur per pound of body weight, with a maximum of 10 mL per injection site.
- Treatment should be repeated at 24 hour intervals, and continued for 48 hours after clinical signs have disappeared but should not exceed 10 days.

IMPORTANT SAFETY INFORMATION:
People with known hypersensitivity to penicillin or cephalosporins should avoid exposure to NAXCEL. Do not use in horses intended for human consumption. Do not use in animals found to be hypersensitive to the product. The administration of antimicrobials to horses under conditions of stress may be associated with acute diarrhea that could be fatal. See full Prescribing Information, attached.

Sterile Water

USES:
For usage in diluting Naxcel Sterile Powder.

SUPPLIED:
- 80 mL (for 4g Naxcel)

TUCOPRIM®
(trimethoprim and sulfadiazine powder)

USES:
Indicated in horses where potent systemic antibacterial action against sensitive organisms is required. Trimethoprim/sulfadiazine is indicated where the control of bacterial infections is required during the treatment of: acute strangles, acute urogenital infections, respiratory tract infections, and wound infections or abscesses.

SUPPLIED:
- 400 gram pail
- 2000 gram pail

KEY FACTS:
- The recommended dose is 3.75 grams TUCOPRIM Powder per 50 kg (110 lbs) body weight per day. Each level, loose-filled scoop contains approximately 15 grams which is sufficient to treat 200 kg (440 lbs) of body weight.
- Administer orally in a small amount of palatable food.
- The usual course of treatment is a single, daily dose for five to seven days, continuing acute infection therapy for two to three days after clinical signs have subsided.
- Low toxicity.

IMPORTANT SAFETY INFORMATION:
TUCOPRIM should not be used in horses showing liver parenchymal damage, blood dyscrasias or in those with a history of sulfonamide sensitivity. Do not use in horses intended for human consumption. See full Prescribing Information, attached.
**NOLVASAN® Solution**  
*(chlorhexidine diacetate)*

**USES:**  
Powerful cleaner, disinfectant and deodorizer recommended for the disinfection of inanimate objects.

**SUPPLIED:**  
- 1 gallon

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**NOLVASAN® S**  
*(chlorhexidine diacetate)*

**USES:**  
Disinfects inanimate objects to aid in the control of many viruses.

**SUPPLIED:**  
- 16 oz.
- 1 gallon

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**NOLVASAN® Skin and Wound Cleanser**  
*(chlorhexidine)*

**USES:**  
Powerful cleaner, disinfectant and deodorizer recommended for the disinfection of inanimate objects.

**SUPPLIED:**  
- 4 oz

**KEY FACTS:**
- For wound cleansing rinse the area to be cleansed with clean water. A moistened gauze pad may be used to apply a small amount of Nolvasan Skin and Wound Cleanser to the affected area. Gently cleanse for 2-4 minutes. Additional water may be needed to obtain adequate sudsing.
- Repeat cleaning if necessary. Wipe away excess foam with a clean gauze pad.
- After cleansing, an antiseptic ointment or suitable dressing may be applied.
- For general skin cleansing thoroughly rinse area to be cleansed with water, apply sufficient Nolvasan Skin and Wound Cleanser and wash gently. Rinse again thoroughly.

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**NOLVASAN® Surgical Scrub**  
*(chlorhexidine)*

**USES:**  
Antimicrobial skin and wound cleanser.

**SUPPLIED:**  
- 1 gallon

**KEY FACTS:**
- Rinse the area to be cleansed with clean water.
- Apply 1 to 5 mL of Nolvasan Surgical Scrub to the area and wash with a sponge or brush for 2 to 4 minutes.
- It may be necessary to apply additional water to obtain adequate sudsing. Wipe away excess foam with sterile sponge.
**ARVAC®
Equine Arteritis Virus Vaccine**

**USES:**
Equine Arteritis Virus (EAV) vaccine for the vaccination of healthy non-stressed adult horses as an aid in the prevention of viral abortion and respiratory infection due to equine arteritis virus.

**SUPPLIED:**
- 10 x 1 dose vial

**KEY FACTS:**
- ARVAC vaccine contains a modified-live equine arteritis virus.
- Administer one 1 mL dose intramuscularly.
- Vaccinate males and young animals at any time, but stallions should be vaccinated not less than 3 weeks prior to breeding.
- Vaccinate mares preferably as maidens or when open.
- Mares in foal should not be vaccinated until after foaling and then not less than 3 weeks prior to breeding.
- Maiden and barren mares may be vaccinated anytime but should be vaccinated not less than 3 weeks prior to breeding.
- Annual booster dose is recommended.
- Store in the dark at 2° to 7°C (35° to 45°F).
- Use entire contents within 60 minutes after rehydration.
- Burn container and unused contents.
- Do not vaccinate within 21 days before slaughter.
- In case of anaphylactoid reaction, administer epinephrine.

**EQUILOID INNOVATOR®
Encephalomyelitis Vaccine-Tetanus Toxoid**

**USES:**
For the vaccination of healthy horses as an aid in the prevention of equine encephalomyelitis due to eastern and western viruses, and tetanus.

**SUPPLIED:**
- 12 x 1 dose syringe
- 10 dose vial

**KEY FACTS:**
- Inject one 1 mL dose intramuscularly using aseptic technique, administer a second 1 mL dose 3 to 4 weeks after first dose.
- A 1 mL booster dose should be given annually.
- Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.
- Use entire contents when first opened.
- In some instances, transient local reactions may occur at the injection site.
- Do not use within 21 days of slaughter.
- In case of anaphylactoid reaction, administer epinephrine.

**EQUIVAC INNOVATOR® EHV-1/4
Rhinopneumonitis Vaccine**

**USES:**
For the vaccination of healthy horses as an aid in the prevention of equine rhinopneumonitis due to type 1 and 4 equine herpesviruses.

**SUPPLIED:**
- 10 dose vial

**KEY FACTS:**
- Inject one 1 mL dose intramuscularly using aseptic technique, administer a second 1 mL dose 3 to 4 weeks after first dose.
- A 1 mL booster dose should be given annually.
- Use entire contents when first opened.
- In some instances, transient local reactions may occur at the injection site.
- Do not use within 21 days of slaughter.
- In case of anaphylactoid reaction, administer epinephrine.
FLUVAC INNOVATOR®
Equine Influenza Vaccine

USES:
FLUVAC INNOVATOR is for the vaccination of healthy horses as an aid in prevention of equine influenza due to type A2 viruses.

SUPPLIED:
- 12 x 1 dose syringes
- 10 dose vial

KEY FACTS:
- The only vaccine with equine influenza virus (EIV) strain KY '97 that has demonstrated protection against heterologous challenge with EIV strain OH '03.
- Since 2002, the vaccine strain in FLUVAC INNOVATOR has been demonstrated to be effective against six emergent strains of equine influenza including Richmond 07.
- Only INNOVATOR vaccines are adjuvanted with METASTIM® for improved immune response.
- Inject 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose in unvaccinated or naïve horses.
- A 1 mL annual revaccination in previously vaccinated horses is recommended.
- Use entire contents when first opened.
- In some instances, transient local reactions may occur at the injection site.
- Do not use within 21 days of slaughter.
- In case of anaphylactoid reaction, administer epinephrine.

FLUVAC INNOVATOR® EHV-4/1
Rhinopneumonitis-Equine Influenza Vaccine

USES:
For intramuscular vaccination of healthy horses as an aid in the prevention of equine rhinopneumonitis due to types 1 and 4 herpesviruses, and equine influenza due to the type A2 viruses.

SUPPLIED:
- 12 x 1 dose syringe
- 10 dose vial

KEY FACTS:
- Helps deliver demonstrated protection against circulating contemporary equine influenza virus (EIV) strains.
- Since 2002, the vaccine strain in FLUVAC INNOVATOR has been demonstrated to be effective against six emergent strains of equine influenza including Richmond 07.
- The only vaccines shown to help prevent clinical disease in 100% of vaccinated horses following EIV OH '03 challenge.
- FLUVAC INNOVATOR vaccines contain the Kentucky/97 subtype of EIV and METASTIM, a proprietary oil emulsion adjuvant with immunostimulating properties.
- Inject 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose.
- A 1 mL annual revaccination in previously vaccinated horses is recommended.
- Use entire contents when first opened.
- In some instances, transient local reactions may occur at the injection site.
- Do not use within 21 days of slaughter.
- In case of anaphylactoid reaction, administer epinephrine.

4 Data on file, Study Report No. 14OREQBio-1, Zoetis Inc.
**FLUVAC INNOVATOR® 4**  
Encephalomyelitis-Influenza Vaccine-Tetanus Toxoid

**USES:**  
For vaccination of healthy horses as an aid in the prevention of equine encephalomyelitis due to Eastern and Western viruses, equine influenza due to type A₂ viruses, and tetanus.

**SUPPLIED:**  
• 12 x 1 dose syringe  
• 10 dose vial

**KEY FACTS:**  
• Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose.  
• Since 2002, the vaccine strain in FLUVAC INNOVATOR has been demonstrated to be effective against six emergent strains of equine influenza including Richmond 07.  
• A 1 mL booster dose should be given annually.  
• Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.  
• Use entire contents when first opened.  
• In some instances, transient local reactions may occur at the injection site.  
• Do not vaccinate within 21 days before slaughter.  
• In case of anaphylactoid reaction, administer epinephrine.

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**FLUVAC INNOVATOR® 6**  
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine-Tetanus Toxoid

**USES:**  
For vaccination of healthy horses as an aid in the prevention of equine encephalomyelitis due to Eastern, Western and Venezuelan viruses, equine rhinopneumonitis due to type 1 and 4 herpesviruses, equine influenza due to type A₁ viruses, and tetanus.

**SUPPLIED:**  
• 12 x 1 dose syringe  
• 10 dose vial

**KEY FACTS:**  
• Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose.  
• Since 2002, the vaccine strain in FLUVAC INNOVATOR has been demonstrated to be effective against six emergent strains of equine influenza including Richmond 07.  
• A 1 mL booster dose should be given annually.  
• Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.  
• Use entire contents when first opened.  
• In some instances, transient local reactions may occur at the injection site.  
• Do not vaccinate within 21 days before slaughter.  
• In case of anaphylactoid reaction, administer epinephrine.

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¹ Data on file, Study Report No. 14OREGBIO-1, Zoetis Inc.
**FLUVAC INNOVATOR® 5**  
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine-Tetanus Toxoid

**USES:**  
For vaccination of healthy horses as an aid in the prevention of equine encephalomyelitis due to Eastern and Western viruses, equine rhinopneumonitis due to type 1 and 4 herpesviruses, equine influenza due to type A, viruses, and tetanus.

**SUPPLIED:**  
- 12 x 1 dose syringes  
- 10 dose vials

**KEY FACTS:**  
- Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose.  
- Since 2002, the vaccine strain in FLUVAC INNOVATOR has been demonstrated to be effective against six emergent strains of equine influenza including Richmond 07.  
- A 1 mL booster dose should be given annually.  
- Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.  
- Use entire contents when first opened.  
- In some instances, transient local reactions may occur at the injection site.  
- Do not vaccinate within 21 days before slaughter.  
- In case of anaphylactoid reaction, administer epinephrine.

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**FLUVAC INNOVATOR® Triple-E FT®**  
Encephalomyelitis-Influenza Vaccine-Tetanus Toxoid

**USES:**  
For vaccination of healthy horses 10 months of age or older as an aid in the prevention of equine encephalomyelitis due to Eastern, Western and Venezuelan viruses, equine influenza due to type A, viruses, and tetanus.

**SUPPLIED:**  
- 12 x 1 dose syringe  
- 10 dose vial

**KEY FACTS:**  
- Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose.  
- Since 2002, the vaccine strain in FLUVAC INNOVATOR has been demonstrated to be effective against six emergent strains of equine influenza including Richmond 07.  
- A 1 mL booster dose should be given annually.  
- Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.  
- Use entire contents when first opened.  
- In some instances, transient local reactions may occur at the injection site.  
- Do not vaccinate within 21 days before slaughter.  
- In case of anaphylactoid reaction, administer epinephrine.

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7 Data on file, Study Report No. 14OREOBIO-1, Zoetis Inc.
**PINNACLE® I.N.**

**USES:**
For the vaccination of healthy horses as an aid in the prevention of disease caused by *Streptococcus equi*.

**SUPPLIED:**
• 10 x 1 dose vial

**KEY FACTS:**
• The only two-dose modified-live vaccine developed to help prevent strangles caused by *Streptococcus equi*.
• Intranasal administration helps provide a “more natural” immune response, stimulating innate and mucosal immunity at the site of natural infection.
• Pinnacle I.N. utilizes a specially designed cannula that helps deliver the vaccine to the pharyngeal (throat) area.
• Aseptically rehydrate with the entire contents of the accompanying sterile diluent. Instill the entire rehydrated vaccine into one nostril using a syringe with applicator tip. Administer a second dose 2 to 3 weeks later.
• Annual revaccination is recommended.
• For intranasal use only. Do not administer by any other route than intranasal.
• Use entire contents when first opened.
• After administration a small number of horses may experience non-contagious transitory upper respiratory signs including nasal discharge and lymphadenectasis. Purpura hemorrhagica may be seen in hypersensitive individuals following exposure to streptococcal proteins.
• Do not vaccinate within 30 days before slaughter.
• In case of anaphylactoid reaction, administer epinephrine.

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**PNEUMABORT-K® + 1b**

**Equine Rhinopneumonitis Vaccine**

**USES:**
The only equine vaccine labeled for use in pregnant mares to aid in the prevention of abortion due to EHV-1 infections, as well as to help prevent respiratory infections caused by equine herpesvirus (EHV)-1p and EHV-1b.

**SUPPLIED:**
• 12 x 1 dose syringe
• 10 dose vial

**KEY FACTS:**
• Broad protection—the only equine vaccine labeled for use in pregnant mares as an aid in the prevention of abortion due to EHV-1 infections, as well as to help prevent respiratory infections caused by equine herpesvirus (EHV)-1p and EHV-1b.
• Prevalence—the 1b subgroup of EHV-1 continues to be an important group, as are abortions associated with EHV-1 infections.¹
• PNEUMABORT-K +1b is uniquely adjuvanted for improved immune responses.
• Recommended for whole-herd management, including geldings, stallions and mares where there is evidence of EHV-1 in the herd population.
• For pregnant mares, aseptically administer one 2 mL dose intramuscularly during the 5th, 7th and 9th months of pregnancy. Revaccinate annually at the 5th, 7th and 9th months of pregnancy.
• For young horses, aseptically administer one 2 mL dose intramuscularly followed by a second 2 mL dose 3 to 4 weeks later. Revaccinate with a single 2 mL dose 6 months after the second primary dose and annually thereafter.
• To insure proper placement and retention of the vaccine, inject deep into the heavy muscles of the hindquarter.
• Mild exercise to promote absorption is recommended for one week after injection.
• Maiden and barren mares kept in barn- or pasture-contact with vaccinated pregnant mares should be vaccinated on the same schedule as the pregnant mares with which they are in contact. Mares more than five months pregnant at the time of arrival on a farm should be vaccinated upon arrival and at two-month intervals until foaling.
• Pregnant mares that are in contact with mares that have aborted equine herpesvirus 1 infected fetuses should be vaccinated. Such vaccination may provide immunity for those mares in the group which are not incubating an abortigenic infection at the time of vaccination.
• Do not vaccinate within 60 days before slaughter.
• In case of anaphylactoid reaction, administer epinephrine.

TETANUS ANTITOXIN

USES:
For the use in domestic animals for the prevention and treatment of tetanus.

SUPPLIED:
• 10 x 1,500 IU vial

KEY FACTS:
• 1500 units, minimum, if injected within 24 hours of exposure.
• Administer subcutaneously, intravenously or intraperitoneally.
• Increase dose relative to the lapse of time following exposure to as much as 30,000 to 100,000 units in animals which are showing symptoms.
• It should always be remembered that good nursing and proper supportive treatment, in addition to the administration of antitoxin, will help improve the patient’s chances for recovery.
• This product is prepared from the blood of horses repeatedly injected with large doses of the toxin from Clostridium tetani.
• It has been reported that biologicals of equine origin may in some manner be associated with the development of hepatitis (Theiler’s disease) when injected into equine species. The incidence of Theiler’s disease is rare and in affected animals may be manifested as hepatitis, icterus, anorexia, emaciation and death.
• Use entire contents when first opened.
• Do not vaccinate within 21 days before slaughter.
• In case of anaphylactoid reaction, administer epinephrine.

EQUINE ROTAVIRUS VACCINE*

Conditional License

USES:
For the vaccination of pregnant mares to provide the passive transfer of antibodies to foals against equine rotavirus.

SUPPLIED:
• 10 dose vial

KEY FACTS:
• Pregnant mares, inject one 1 mL dose intramuscularly at the eighth month of pregnancy using aseptic technique.
• Administer a second 1 mL dose one month later (i.e., at the ninth month of pregnancy).
• A third 1 mL dose is then given one month later (i.e., at the tenth month of pregnancy).
• Each pregnancy requires vaccination with 3 doses.
• Use entire contents when first opened.
• Do not vaccinate within 21 days before slaughter.
• In case of anaphylactoid reaction, administer epinephrine.

* This product is conditionally licensed by the USDA while additional efficacy and potency data are being developed.
**TRIPLE-E T INNOVATOR® Encephalomyelitis Vaccine-Tetanus Toxoid**

**USES:**
For intramuscular vaccination of healthy horses as an aid in the prevention of equine encephalomyelitis due to Eastern, Western and Venezuelan viruses, and tetanus.

**SUPPLIED:**
- 12 x 1 dose syringe
- 10 dose vial

**KEY FACTS:**
- Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose. A 1 mL booster dose should be given annually.
- Early revaccination may be advisable when horses are faced with an outbreak or other conditions which might make heavy exposure likely.
- A 1 mL booster dose should be given annually.
- In some instances, transient local reactions may occur at the injection site.
- Do not vaccinate within 21 days before slaughter.
- In case of anaphylactoid reaction, administer epinephrine.

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**TETANUS TOXOID**

**USES:**
For the vaccination of healthy horses as an aid in the prevention of tetanus.

**SUPPLIED:**
- 12 x 1 dose syringe
- 10 dose vial

**KEY FACTS:**
- Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 4 to 8 weeks after the first dose. A 1 mL booster dose should be given annually.
- The MetaStim® adjuvant is added to enhance the immune response and to promote the proper rate of vaccine absorption following inoculation.
- Protective tetanus antibody titers usually occur two weeks after the second injection of the initial series. In the event of injury during the course of the initial vaccination program, or if annual boosters have not been given, a prophylactic dose of at least 1500 units of tetanus antitoxin should be given.
- Transitory local reactions at the injection site may occur.
- Do not vaccinate within 21 days before slaughter.
- In case of anaphylactoid reaction, administer epinephrine.
WEST NILE-INNOVATOR®
West Nile Virus Vaccine

USES:
For intramuscular vaccination of healthy horses 10 months of age or older as an aid in the prevention of viremia caused by West Nile Virus (WNV).

SUPPLIED:
- 12 x 1 dose syringe
- 10 dose vial

KEY FACTS:
- Efficacy of 96.7% demonstrated in independent field study with almost 900 horses.
- Antigen-specific Cell-mediated Immunity as early as 5 days after first vaccination in naïve horse.
- Adjuvanted with Metastim dual-phase adjuvant for enhanced efficacy and safety.
- Supported by the Equine Immunization Support Guarantee for peace of mind.
- The veterinarian’s #1 choice for mosquito-borne disease protection.
- The vaccine credited for helping reduce the number of equine WNV cases by nearly 70 percent from 2002 to 2003.
- Helps stimulate fast, antigen-specific, cell-mediated and humoral responses against WNV.
- Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 6 weeks after the first dose in unvaccinated or naïve horses.
- A 1 mL revaccination should be given annually in previously vaccinated horses.
- Use entire contents when first opened.
- In some instances, transient local reactions may occur at the injection site.
- Do not vaccinate within 21 days before slaughter.
- In case of anaphylactoid reaction, administer epinephrine.

WEST NILE-INNOVATOR® + EW
Encephalomyelitis-West Nile Virus Vaccine

USES:
For vaccination of healthy horses as an aid in the prevention of viremia caused by West Nile virus, and as an aid in the prevention of equine encephalomyelitis due to Eastern and Western viruses.

SUPPLIED:
- 10 dose vial

KEY FACTS:
- Efficacy of the West Nile fraction was demonstrated in horses that received two doses of the vaccine and were challenged one year post-vaccination with West Nile virus.
- Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose.
- A 1 mL booster dose should be given annually.
- Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.
- Use entire contents when first opened.
- In some instances, transient local reactions may occur at the injection site.
- Do not vaccinate within 21 days before slaughter.
- In case of anaphylactoid reaction, administer epinephrine.

WEST NILE-INNOVATOR® + EWT
Encephalomyelitis-West Nile Virus Vaccine-Tetanus Toxoid

USES:
For vaccination of healthy horses as an aid in the prevention of viremia caused by West Nile virus, and as an aid in the prevention of equine encephalomyelitis due to Eastern and Western viruses, and tetanus.

SUPPLIED:
• 12 x 1 dose syringe
• 10 dose vial

KEY FACTS:
• Efficacy of the West Nile fraction was demonstrated in horses that received two doses of the vaccine and were challenged one year post-vaccination with West Nile virus.
• Inject one 1 mL dose intramuscularly using aseptic technique. Administer a second 1 mL dose 3 to 4 weeks after the first dose.
• A 1 mL booster dose should be given annually.
• Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.
• Use entire contents when first opened.
• In some instances, transient local reactions may occur at the injection site.
• Do not vaccinate within 21 days before slaughter.
• In case of anaphylactoid reaction, administer epinephrine.

WEST NILE-INNOVATOR® + VEWT
Encephalomyelitis-West Nile Virus Vaccine-Tetanus Toxoid

USES:
For vaccination of healthy horses as an aid in the prevention of viremia caused by West Nile virus, and as an aid in the prevention of equine encephalomyelitis due to Eastern, Western and Venezuelan viruses, and tetanus.

SUPPLIED:
• 12 x 1 dose syringe
• 10 dose vial

KEY FACTS:
• Efficacy of the West Nile fraction was demonstrated in horses that received two doses of the vaccine and were challenged one year post-vaccination with West Nile virus.
• Inject one 1 mL dose intramuscularly using aseptic technique.
• Administer a second 1 mL dose 3 to 4 weeks after the first dose.
• A 1 mL booster dose should be given annually.
• Early revaccination may be advisable when horses are faced with an outbreak or with other conditions which might make heavy exposure likely.
• Use entire contents when first opened.
• In some instances, transient local reactions may occur at the injection site.
• Do not vaccinate within 21 days before slaughter.
• In case of anaphylactoid reaction, administer epinephrine.
ZYLEXIS®
Parapox Ovis Virus Immunomodulator

USES:
Zylexis is an inactivated (killed) Parapox Ovis Virus Immunomodulator that has demonstrated efficacy and safety in stimulating the horse’s immune response to aid in the reduction of equine upper respiratory disease associated with equine herpesvirus (EHV) types 1 and 4 infections.

SUPPLIED:
• 5 x 1 dose vial

KEY FACTS:
• One 2 mL injection on days 0, 2 & 9 by intramuscular route.
• Aids in the reduction of upper respiratory disease associated with equine herpesvirus types 1 and 4.
• ZYLEXIS treated horses showed significantly lower purulent nasal discharge (p<0.01) and clinical signs (p<0.01) than non-treated control horses.13
• Less days of mucopurulent nasal discharge were seen in ZYLEXIS treated horses vs. the control group.13
• Retreatment is recommended during subsequent disease episodes or prior to stress-inducing situations.
• EHV 1 & 4 infections can be easily triggered by common stressors to horses including trailering, competition, breeding and environmental changes.
• Use entire contents when first opened.
• Do not vaccinate within 21 days before slaughter.
• In case of an anaphylactoid reaction, administer epinephrine or equivalent.


Equine Immunization Support Guarantee (ISG)

Zoetis will support reasonable diagnostic and treatment costs up to $5,000 if a horse properly vaccinated with one of our vaccine antigens contracts the corresponding equine disease.

EQUINE VETERINARIAN BENEFITS:
• Encourages horse owners to seek veterinary expertise and advice.
• Helps extend protection afforded by our INNOVATOR® line of quality vaccines.
• Reimburses clients up to $5,000 in the event of a vaccine break.
• Benefits applicable if the animal is properly vaccinated by a licensed veterinarian.

EQUINE HORSE OWNER BENEFITS:
• Offers peace of mind by helping to protect your horse against infectious diseases — an important responsibility.
• Builds partnership with your veterinarian when caring for your horse.
• Available at no extra cost to you.
• Reimburses you up to $5,000 for treatment and diagnostic costs.
• Provides an ongoing record of vaccinations.

DISEASES COVERED BY THE EQUINE ISG:
All products under the Zoetis WEST NILE-INNOVATOR® and FLUVAC INNOVATOR® line of vaccines are eligible for the Equine ISG. This includes vaccines against the following diseases:
• West Nile
• Equine Influenza
• Tetanus
• Eastern Equine Encephalomyelitis (EEE)
• Equine Herpesvirus 1 and 4 (respiratory)
• Western Equine Encephalomyelitis (WEE)
• Venezuelan Equine Encephalomyelitis (VEE)

Please contact your local Zoetis representative to find out more about the Equine Immunization Support Guarantee.
Zoetis is proud to partner with veterinarians to assure horse owners that their horses are receiving the best possible health care and disease protection.

• Program offers direct financial support specific to lack of vaccine efficacy for any properly vaccinated horse, pony or mule. Does not include any other adverse events associated with vaccine administration.

• Horse must be vaccinated by a licensed veterinarian with an established client-patient relationship.

• Veterinarian or clinic must be the primary point of contact for this support program to be valid. Zoetis will direct all requests from horse owners, breeders, etc., to the vaccinating veterinarian, who in turn will need to file the support request on their behalf.

• At the time of the support request, veterinarians must collaborate with Zoetis Veterinary Medical Information and Product Support (VMIPS) in designing an appropriate diagnostic and treatment regimen. A diagnosis must be made using criteria predetermined by VMIPS. To contact VMIPS, call 888-ZOETIS1 (888-963-8471).

• Veterinarians must submit a copy of medical records pertinent to the case, including vaccine brand, serial number and date of vaccination.

• Support requests involving foals less than 6 months of age, or involving onset of disease within three weeks of completing the initial immunization series, are not covered.

• Horse must have received an age-appropriate, initial vaccination series per the vaccine label. A Zoetis vaccine must be the most recent vaccine used in the series.

• All payments made under the immunization support program may require a signed consent form from the veterinarian and/or horse owner.

ZOETIS RESERVES THE RIGHT TO MODIFY THIS PROGRAM AT ANY TIME AND FOR ANY REASON.

Horse Name

Veterinarian Name

Date

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FLUVAC INNOVATOR®

EHV-4/1

TRIPLE-ET INNOVATOR®

FLUVAC INNOVATOR®

TRIPLE-E FT®

EQUIVAC ™

EHV-1/4

WEST NILE- INNOVATOR® + EWT

WEST NILE- INNOVATOR® + VEWT

EQUINE ROTAVIRUS

TETANUS ANTITOXIN

TETANUS TOXOID

Pinnacle® I.N.

ARVAC®
A BROAD LINE OF VACCINES:

WEST NILE-INNOVATOR®
WEST NILE-INNOVATOR® + EW
WEST NILE-INNOVATOR® + EWT
WEST NILE-INNOVATOR® + VEWT
FLUVAC INNOVATOR® EHV- 4/1
FLUVAC INNOVATOR® 4
FLUVAC INNOVATOR® 5
FLUVAC INNOVATOR® 6
FLUVAC INNOVATOR®
FLUVAC INNOVATOR® Triple-E FT®
EQUILOID INNOVATOR®
TRIPLE-E T INNOVATOR®
PINNACLE® I.N.*
PNEUMABORT-K® + 1b
EQUIVAC INNOVATOR® EHV-1/4
TETANUS ANTITOXIN
TETANUS TOXOID
ARVAC®
EQUINE ROTAVIRUS*,**

* Available only through a veterinarian
** This product license is conditional. Efficacy and potency test studies are in progress. Please consult your veterinarian.
**ANTHELCIDE® EQ Paste**  
*(oxibendazole)*

**USES:**  
Broad-spectrum equine dewormer containing the active ingredient oxibendazole.

**SUPPLIED:**  
• 24 gram syringe

**KEY FACTS:**  
• Paste is approved for the removal and control of large strongyles (*Strongyulus edentatus, S. equinus, S. vulgaris*); small strongyles (species of the genera *Cycicostephanus, Cycicocyclus, Cyathostomum, Triodontophorus, Cylicodontophorus,* and *Gyalocephalus*); large roundworms (*Parascaris equorum*); pinworms (*Oxyuris equi*), including various larval stages and threadworms (*Strongyloides westeri*).

• One syringe doses up to 1,200-lb body weight.

• Shows efficacy against benzimidazole-resistant strongyles and has a known wide margin of safety.\(^{14,15}\)


**QUEST® Gel**  
*(moxidectin)*

**USES:**  
Protect against large and small strongyles, roundworms, pinworms, hairworms, stomach worms, bots, and encysted small strongyles.

**SUPPLIED:**  
• 11.3 g syringe

**KEY FACTS:**  
• QUEST/QUEST Plus are the only FDA-approved broad-spectrum equine dewormers labeled to suppress production of small strongyle eggs for 84 days.

• One tube of QUEST covers more parasitic groups than five double-dose tubes of fenbendazole.\(^{16}\)

• Approved for use in breeding mares and stallions, and foals six months of age and older.

• Clear gel dissolves instantly for an easier deworming process.

• Comes in ready to use syringes, for up to 1150-lb body weight, at 50 lb increments.

**IMPORTANT SAFETY INFORMATION:**  
Do not use QUEST Gel or QUEST PLUS Gel in foals less than 6 months of age or in sick, debilitated and underweight horses. Do not use in other animal species, as severe adverse reactions, including fatalities in dogs, may result.

**QUEST® PLUS Gel**
*(moxidectin/praziquantel)*

**USES:**
Protect against large and small strongyles, roundworms, pinworms, hairworms, stomach worms, bots, tapeworm and encysted small strongyles.

**SUPPLIED:**
- 11.6 g syringe

**KEY FACTS:**
- Effective in the treatment and control of tapeworm infections.
- QUEST/QUEST Plus are the only FDA-approved broad-spectrum equine dewormers labeled to suppress production of small strongyle eggs for 84 days.
- One tube of QUEST PLUS covers the same parasitic groups as six other tubes (five double-dose tubes of fenbendazole and one tube of ivermectin/praziquantel).\(^7\)
- Approved for use horses and ponies six months of age and older.
- Clear gel dissolves instantly for an easier deworming process.
- Comes in ready to use syringes, for up to 1250-lb body weight, at 50 lb increments.

**IMPORTANT SAFETY INFORMATION:**
Do not use QUEST Gel or QUEST PLUS Gel in foals less than 6 months of age or in sick, debilitated and underweight horses. Do not use in other animal species, as severe adverse reactions, including fatalities in dogs, may result.


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**SOLITUDE® IGR Feed-Through Pellet**
*(2.12% cyromazine)*

**USES:**
Insect growth regulator that inhibits development of the exoskeleton in immature house and stable flies, preventing them from becoming adults.

**SUPPLIED:**
- 6 lb pail (120 doses)
- 20 lb pail (640 doses)

**KEY FACTS:**
- SOLITUDE IGR can safely and dramatically reduce the number of flies around horse operations because it prevents immature flies from developing into adults.
- Feed through fly preventative which, when mixed 1/2 ounce into a horse’s ration daily, will prevent house and stable flies in and around horses, horse barns, stables, paddocks and race tracks.
- 1/2 ounce scoop of SOLITUDE IGR per day top dressed onto grain or mixed with the horses total ration, no matter the size or weight of the horse.
**STRONGID® Paste**  
(*pyranteI pamoate*)

**USES:**  
Equine dewormer containing pyrantel, a compound from the tetrahydropyrimidine class. STRONGID Paste is approved for the removal and control of mature infections of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.

**SUPPLIED:**  
- 11.6 g syringe

**KEY FACTS:**  
- Effective against mature infections of ascarids, large strongyles, small strongyles and pinworms.
- Demonstrated effective against benzimidazole resistant strongyles.
- Safe for use in horses and ponies.
- Convenient disposable syringe treats up to 1,200-lb body weight.
- For maximum control of parasitism, it is recommended that foals (2 to 8 months of age) be dosed every fourth (4) weeks.
- To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated one (1) month prior to the anticipated foaling date followed by retreatment 10 days to two (2) weeks after birth of foal. Horses and ponies over eight (8) months of age should be routinely dosed every six (6) weeks.

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**STRONGID® C/C 2X Equine Anthelmintic**  
(*pyrantel tartrate*)

**USES:**  
Equine anthelmintic designed to be fed on a daily basis to provide a continuous level of pyrantel in the intestinal tract. STRONGID C/C 2X are approved for the prevention of *Strongylus vulgaris* larval infestation in horses and for control of large strongyles–adults (*S. vulgaris, S. edentatus*); small strongyles–adults and 4th-stage larvae (*Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp., Cylicodontophorus spp., Poteriostomum spp., Triodontophorus spp.*); pinworms–adults and 4th-stage larvae (*Oxyuris equi*); ascarids–adults and 4th-stage larvae (*Parascaris equorum*).

**SUPPLIED:**  
- Strongid C 25 lb pail (100 doses for a 1,000 lb horse)
- Strongid C 2X 10 lb pail (80 doses for a 1,000 lb horse)
- Strongid C 2X 50 lb bag (400 doses for a 1,000 lb horse)

**KEY FACTS:**  
- Daily feeding of Strongid C/C 2X kills *S. vulgaris* larvae before they can damage vital organs or grow to adulthood and produce eggs that contaminate pastures.
- Strongid C 2X has concentrated double strength which is effective at lower volumes.
- Use of a daily dewormer help break the parasite life cycle, preventing reinfection and costly tissue damage.
- Daily use of Strongid C/C 2X in the last 30 days of gestation is a safe effective method of reducing foal exposure to parasites.
- Easy to top dress onto a daily grain ration.
- Helps prevent parasite build-up on a daily basis which may lead to better nutrition, health, appearance and performance.
- Particularly useful where stocking density is high, pasture rotation is impossible, or exposure is continuous.
- 1 oz of STRONGID C per 250 lb of body weight.
- 0.5 oz of STRONGID C 2X per 250 lb of body weight.

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STRONGID® T Suspension
(pyrantel pamoate)

USES:
For the removal and control of mature infections of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); pinworms (Oxyurus equi); large roundworms (Parascaris equorum); and small strongyles in horses and ponies.

SUPPLIED:
• Quart containing 15 doses for a 1,000 lb horse

KEY FACTS:
• Effective against mature infections of ascarids, large strongyles, small strongyles and pinworms.
• Caramel flavored and easy to dose at 6ml per 100 pounds body weight.
• May be administered by means of a stomach tube, dose syringe or by mixing into the feed.
• For maximum control of parasitism, it is recommended that foals (2 to 8 months of age) be dosed every four (4) weeks.
• To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated one (1) month prior to the anticipated foaling date followed by retreatment 10 days to two (2) weeks after birth of foal.
• Horses and ponies over eight (8) months of age should be routinely dosed every six (6) weeks.

IMPORTANT SAFETY INFORMATION:
STRONGID T is not recommended for use in severely debilitated animals. Not for use in horses intended for human consumption. See full Prescribing Information, attached.
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<th>Trade Name</th>
<th>Active</th>
<th># of Tubes</th>
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<th>SMALL STRONGYLES</th>
<th>ROUNDWORMS</th>
<th>PINWORMS</th>
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<th>STOMACH WORMS</th>
<th>BOTS</th>
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CARBOCAINE®-V Sterile Aqueous Solution
(mepivacaine hydrochloride)

USES:
Recommended for infiltration, nerve block, intra-articular and epidural anesthesia. It has also been found useful for topical anesthesia of the laryngeal mucosa prior to ventriculectomy.

SUPPLIED:
• 50 mL multiple dose vial

KEY FACTS:
• Dosage varies considerably depending on anesthetic technique, body area to be desensitized and the surgical procedure.
• The drug produces complete and effective anesthesia at dosages that are no more than half those need when procaine is used.
• For nerve block 3 to 15 mL is recommended in the diagnosis of lameness, firing, pain relief in osteoarthritis, and navicular disease.
• For epidural anesthesia 5 to 20 mL is recommended.
• For intra-articular anesthesia 10 to 15 mL is recommended in the diagnosis of bone and bog spavin, removal of fractural chips, and arthritis.
• For anesthesia it may be administered topically, by infiltration or by a combination of the two.

IMPORTANT SAFETY INFORMATION:
Do not use CARBOCAINE V in horses intended for human consumption. Avoid intravenous administration. See full Prescribing Information, attached.

DORMOSEDAN®
(detomidine hydrochloride)

USES:
Long lasting sedative for standing procedures such as minor surgeries, diagnostic procedures, wound treatment, transportation, management of colic, general examinations, etc.

SUPPLIED:
• 5 mL
• 20 mL

KEY FACTS:
• Effective standing sedative and analgesic in a single, non-narcotic dose.
• Dormosedan has a graded dose response relationship; higher dosing increases duration of sedation and analgesic effects but does not increase the depth of sedation.
• Can be administered intravenously (IV) or intramuscularly.
• Predictable and effective because of Alpha 2 selectivity; for veterinarians this means no mixing of product and guesswork dosing.
• Dormosedan additional dosing prolongs not deepens sedation.
• Offers a wide margin of safety.
• Proper label use is proven to reduce the cost of re-sedation, compared to other sedation processes.

IMPORTANT SAFETY INFORMATION:
Do not use DORMOSEDAN Sterile Solution in horses with pre-existing atroventricular (AV) or sinoatrial (SA) block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Do not use in anesthetized or sedated horses, or in conditions of shock, severe debilitation or stress due to extreme heat, cold, fatigue or high altitude. Do not use in horses intended for human consumption. Handle dosing syringes with caution to avoid direct exposure to skin, eyes or mouth. See full Prescribing Information, attached.
**DORMOSEDAN® Gel**  
(detomidine hydrochloride)

**USES:**
A convenient solution when horse owners need a mild, standing sedative prior to certain stressful situations or minor, (nonpainful) husbandry procedures.

**SUPPLIED:**
- Syringe

**KEY FACTS:**
- Convenient and safe for a wide variety of procedures.
- Prescribed by the veterinarian, administered by the horse owner.
- FDA approved for mild sedation and restraint of horses at least one year of age.
- Administered sublingually.
- The only standing sedative of its kind.
- Single-dose syringe and is easy for horse owners to administer themselves.
- The duration and level of sedation are dose dependent. At the recommended 40 mcg/kg dose, the onset of sedation was observed at approximately 40 minutes with a duration of sedation lasting between 90 to 180 minutes.

**IMPORTANT SAFETY INFORMATION:**
Do not use DORMOSEDAN Gel in horses with pre-existing atrioventricular (AV) or sinoatrial (SA) block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Do not use in anesthetized or sedated horses, or in conditions of shock, severe debilitation or stress due to extreme heat, cold, fatigue or high altitude. Do not use in horses intended for human consumption. Handle dosing syringes with caution to avoid direct exposure to skin, eyes or mouth. See full Prescribing Information, attached.

**FLUNIXAMINE® Injectable Solution**  
(flunixin meglumine)

**USES:**
For the alleviation of inflammation and pain associated with musculoskeletal disorders. Also recommended for the alleviation of visceral pain associated with colic.

**SUPPLIED:**
- 100 mL
- 250 mL vial

**KEY FACTS:**
- Administer 0.5 mg per pound of body weight once daily for alleviation of pain associated with lameness.
- Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days.
- Onset of activity is within 2 hours. Peak response occurs between 12 and 16 hours, and duration of activity is 24-36 hours.

**IMPORTANT SAFETY INFORMATION:**
Do not use FLUNIXAMINE in horses intended for human consumption. NSAIDS are known to have potential effects on both parturition and estrus cycle. Drug compatibility should be monitored closely in patients requiring adjunctive therapy. See full Prescribing Information, attached.
**KETOFEN® Sterile Solution**  
(*ketoprofen*)

**USES:**  
Non-narcotic, non-steroidal anti-inflammatory agent recommended for the alleviation of inflammation and pain associated with muscoskeletal disorders in horses.

**SUPPLIED:**  
- 50 mL  
- 100 mL

**KEY FACTS:**  
- Recommended dosage is 1 mg/lb of body weight repeated once daily, treatment is administered by intravenous injection and may be repeated for up to five days.

**IMPORTANT SAFETY INFORMATION:**  
KETOFEN should not be used in breeding horses. Do not use in horses intended for human consumption. See full Prescribing Information, attached.

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**TORBUGESIC® Veterinary Injection 10 mg/mL**  
(*butorphanol tartrate*)

**USES:**  
For the relief of pain associated with colic in adult horses and yearlings. Clinical studies have shown that TORBUGESIC alleviates abdominal pain associated with torsion, impaction, intussusception, spasmodic and tympanic colic and postpartum pain.

**SUPPLIED:**  
- 10 mL  
- 50 mL

**KEY FACTS:**  
- Recommended dosage in horses is .1 mg of butorphanol per kg of body weight by intravenous injection, this is equivalent to 5 mL of TORBUGESIC for each 1,000 lbs of body weight.  
- Common side effects in clinical trials was slight ataxia which lasted 3 to 10 minutes.

**IMPORTANT SAFETY INFORMATION:**  
Use TORBUGESIC with caution with other sedative or analgesic drugs as these are likely to produce additive effects. Do not use in breeding horses, weanlings, or foals. Do not use in horses intended for human consumption. See full Prescribing Information, attached.
CLOVITE® Conditioner

USES:
Vitamin supplement containing vitamin A, vitamin D and vitamin B12.

SUPPLIED:
• 5 lb pail
• 25 lb pail

KEY FACTS:
• Suggested dosage for young foals and weanlings is 1 to 2 tablespoons daily; for broodmares 2 tbsp daily; for ponies 1 tbsp daily; for colts, stallions and horses in training dosage is 1 tbsp per 400 lbs of body weight.

LIXOTINIC® LIQUID

USES:
Vitamin-iron and mineral supplement.

SUPPLIED:
• Gallon

KEY FACTS:
• Recommended daily dosage for horses is 1-2 oz.
LUTALYSE® Injection
(dinoprost injection)

USES:
Indicated for the control of the timing of estrus in estrous cycling mares and clinically anestrous mares that have a corpus luteum.

SUPPLIED:
• 30 mL
• 100 mL

KEY FACTS:
• Mares treated with LUTALYSE during diestrus will return to estrus within 2 to 4 days in most cases and ovulate 8 to 12 days after treatment.
• In anestrus mares treatment usually results in regression of the corpus luteum followed by estrus/ovulation.
• In one study with mares in clinical anestrus for an average of 58 days and treated during the breeding season, behavioral estrus was detected in 81 percent at an average time of 3.7 days after injection with 5 mg LUTALYSE; ovulation occurred an average of 7.0 days after treatment.

IMPORTANT SAFETY INFORMATION:
Women of childbearing age and persons with respiratory problems should exercise extreme caution when handling LUTALYSE. LUTALYSE is readily absorbed through the skin and may cause abortion and/or bronchiospasms, therefore spillage on the skin should be washed off immediately with soap and water. Pregnancy status should be determined prior to treatment, as abortion and parturition have been reported. Aseptic technique should be used to reduce the possibility of post-injection clostridial infections. Do not use in horses intended for human consumption. See full Prescribing Information, attached.
KOPERTOX®

USES:
Aid in the treatment of thrush in horses and ponies due to organisms susceptible to copper naphthenate.

SUPPLIED:
• 8 oz
• 16 oz

KEY FACTS:
• Apply daily to affected hoofs with a narrow paint brush until fully healed.

IMPORTANT SAFETY INFORMATION:
Do not use KOPERTOX in horses intended for human consumption.
PEOPLEFIRST™

*Human Capital Solutions*

The industry’s first comprehensive human capital and business management solutions service

Since 2009, PeopleFirst™ Human Capital Solutions has provided owners, managers, supervisors and employees of agricultural operations, veterinary clinics and ranch and farm retail with comprehensive and strategic services to address leadership development, employee training and business objectives and strategies. Find more information on helping build a more productive and profitable business and operation at GrowPeopleFirst.com.

EMPLOYEE SERVICES:

- **Supervisory Certificate Program** — This course, delivered in English and Spanish, develops leadership skills for managers and supervisors to help improve how they run their operation, agribusiness or veterinary practice.

- **Learning Management Portal** — Online technology automates and centralizes employee orientation to ensure everyone develops the right skills to achieve organizational objectives. The portal gives your organization the ability to provide continuous training, track/score completion and customize and formalize learning plans.

- **Customized services** — An array of consultative services can be customized to meet your needs, including full organizational evaluations, engagement and 360-degree feedback, leadership training, change management and executive coaching.

BUSINESS SERVICES:

- **ProfitSolver®** — The ultimate financial diagnostic tool for your veterinary practice.

- **Strategic Planning** — Custom and standard consulting help create a strategic plan for your business by identifying your three-year objectives, aligning your team around your strategic intent and creating an action plan to accomplish your goals.

- **Succession Planning** — We will work with you to develop a plan to transfer your assets. We are experts at facilitating those difficult conversations, with family members or business partners, to satisfy your goals. We’ll work with your own lawyer and accountant to put the plan in place.

- **Marketing Planning** — We’ll work with your staff to develop plans to help your business grow.

- **Customized services** — An array of consultative services can be customized to meet your business needs, client surveys, scenario planning, action planning.

1 ProfitSolver is the registered trademark of Fee Technology, Inc.
PRESCRIBING INFORMATION
**Amiglyde-V®**

**AMIKACIN SULFATE**

Veterinary Solution Equivalent to 250 mg amikacin per mL

**DESCRIPTION**

Amikacin sulfate is a semi-synthetic aminoglycoside antibiotic derived from kanamycin. It is a derivative of 3-deoxy-D-glucopyranosyl-D-glucopyranosyl-(1→6)-[6-amino-6-deoxy-D-glucopyranosyl-(1→4)]-N1-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-, (S)-, sulfate (1:2) (salt).

The dosage form supplied is a sterile, colorless to light straw-colored solution. The solution contains, in addition to amikacin sulfate, USP 2.5% sodium citrate, USP with pH adjusted to 4.5 with sulfuric acid and 0.66% sodium bisulfite added. The multi-dose 12 gram–48 mL vial contains 0.01% benzethonium chloride, USP as a preservative.

**ACTION**

**Antibacterial Activity**

The effectiveness of AMIGLYDE-V (amikacin sulfate) in infections caused by Escherichia coli, Pseudomonas sp and Klebsiella sp has been demonstrated clinically in the horse. In addition, the following microorganisms have been shown to be susceptible to amikacin in vitro, although the clinical significance of this action has not been demonstrated in animals:

- Enterobacter sp
- Proteus mirabilis
- Proteus sp (indole positive)
- Serratia marcescens
- Salmonella sp
- Shigella sp
- Providencia sp
- Citrobacter freundii
- Listeria monocytogenes
- Staphylococcus aureus (both penicillin-resistant and penicillin-sensitive)

The aminoglycoside antibiotics in general have limited activity against gram-positive pathogens, although Staphylococcus aureus and Listeria monocytogenes are susceptible to amikacin as noted above.

Amikacin has been shown to be effective against many aminoglycoside-resistant strains due to its ability to resist degradation by aminoglycoside inactivating enzymes known to affect gentamicin, tobramycin and kanamycin.

**CLINICAL PHARMACOLOGY**

**Endometrial Tissue Concentrations**

Comparisons of amikacin activity in endometrial biopsy tissue following intrauterine infusion with that following intramuscular injection of AMIGLYDE-V in mares demonstrate superior endometrial tissue concentrations when the drug is administered by the intrauterine route.

Intrauterine infusion of 2 grams AMIGLYDE-V daily for three consecutive days in mares results in peak concentrations typically exceeding 40 mcg/g of endometrial biopsy tissue within one hour after infusion. Twenty-four hours after each treatment amikacin activity is still detectable at concentrations averaging 2 to 4 mcg/g. However, the drug is not appreciably absorbed systemically following intrauterine infusion. Endometrial tissue concentrations following intramuscular injection are roughly parallel, but are typically somewhat lower than corresponding serum concentrations of amikacin.

**Safety**

AMIGLYDE-V is non-irritating to equine endometrial tissue when infused into the uterus as directed (see ADMINISTRATION AND DOSAGE). In laboratory animals as well as equine studies, the drug was generally found not to be irritating when injected intravascularly, subcutaneously or intramuscularly.

Although amikacin, like other aminoglycosides, is potentially nephrotoxic, ototoxic and neurotoxic, parenteral (intravenous) administration of AMIGLYDE-V (amikacin sulfate) twice daily at dosages of up to 10 mg/lb for 15 consecutive days in horses resulted in no clinical, laboratory or histopathologic evidence of toxicity.

Intrauterine infusion of 2 grams of AMIGLYDE-V 8 hours prior to breeding by natural service did not impair fertility in mares. Therefore, mares should not be bred for at least 8 hours following uterine infusion.

**INDICATIONS**

AMIGLYDE-V is indicated for the treatment of uterine infections (endometritis, metritis and pyometra) in mares, when caused by susceptible organisms including Escherichia coli, Pseudomonas sp and Klebsiella sp. The use of AMIGLYDE-V in eliminating infections caused by the above organisms has been shown clinically to improve fertility in infected mares.

While nearly all strains of Escherichia coli, Pseudomonas sp and Klebsiella sp, including those that are resistant to gentamicin, kanamycin or other aminoglycosides, are susceptible to amikacin at levels achieved following treatment, it is recommended that the invading organism be cultured and its susceptibility demonstrated as a guide to therapy. Amikacin susceptibility discs, 30 mcg, should be used for determining in vitro susceptibility.

**ADMINISTRATION AND DOSAGE**

For treatment of uterine infections in mares, 2 grams (8 mL) of AMIGLYDE-V, mixed with 200 mL 0.9% Sodium chloride injection, USP and aseptically infused into the uterus daily for three consecutive days, has been found to be the most efficacious dosage.

**CONTRAINDICATIONS**

There are no known contraindications for the use of AMIGLYDE-V in horses other than a history of hypersensitivity to amikacin.

**PRECAUTIONS**

Although AMIGLYDE-V is not absorbed to an appreciable extent following intrauterine infusion, concurrent use of other aminoglycosides should be avoided because of the potential for additive effects.

**REFERENCES**


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Fort Dodge Animal Health
Fort Dodge, Iowa 50501

11800 Revised June 2010 4120JA&P GEO14004

**WARNING**

Do not use in horses intended for human consumption.

In vitro studies have demonstrated that when sperm are exposed to the preservative which is present in the 48 mL vials (250 mg/mL) sperm viability is impaired.

**ADVERSE REACTIONS**

No adverse reactions or other side effects have been reported.
Local Anesthetic with Rapid and Prolonged Effect for Use in Horses

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION
Mepivacaine hydrochloride, 1-methyl-2', 6'-pipexoloxylidide monohydrochloride, is a white, crystalline, odorless powder, readily soluble in water, and very stable in aqueous solution. It is available as a 2% sterile aqueous solution containing sodium chloride (for isotonicity) and 0.1% methylparaben (as preservative). The pH is adjusted with sodium hydroxide or hydrochloric acid.

CLINICAL PHARMACOLOGY
Mepivacaine hydrochloride is a potent local anesthetic whose effectiveness and safety have been well established in human medicine and dentistry. Laboratory and clinical studies in animals have confirmed its value in veterinary medicine. Its anesthetic activity is two to two and one half times that of procaine, and it is equal to or better than that of lidocaine. The compound has shown excellent tissue compatibility in laboratory animals and in horses. Moderate transient edema at the site of injection may occur in rare instances.

CARBOCAINE-V Sterile Aqueous Solution produces rapid and marked local anesthesia lasting for several hours. This enables the veterinarian to proceed with intended manipulations without delay and to complete the work under desensitization which is adequate even for prolonged operations. The innate vasoconstrictive activity of CARBOCAINE-V Sterile Aqueous Solution may be enhanced by the addition of epinephrine at 1:100,000. The addition should be carried out aseptically for current use and any unused portion should be discarded.

INDICATIONS
CARBOCAINE-V Sterile Aqueous Solution is recommended for infiltration, nerve block, intra-articular and epidural anesthesia for horses. It has also been found useful for topical anesthesia of the laryngeal mucosa prior to ventriculectomy. As with other anesthetics, the dosage varies considerably depending on the anesthetic technique, body area to be desensitized and the surgical procedure.

WARNINGS

PRECAUTIONS
When administered by a skilled person, CARBOCAINE-V Sterile Aqueous Solution may be employed safely for local infiltration, for common nerve blocking procedures, and for intra-articular and epidural anesthesia. The following precautions, which are observed with respect to all local anesthetics, also apply to this anesthetic. (1) Injections should always be made aseptically and with frequent aspirations. If blood is aspirated, the needle should be relocated and the injections continued cautiously. (2) When used for epidural anesthesia, care should be taken to avoid injection into the subarachnoid space. The skin should be shaved and sterilized, and the needles used must be sharp and of the proper length. (3) The depth of anesthesia should be checked by pricking the area before manipulations are begun.

DOSAGE AND ADMINISTRATION
Pharmacological studies in various species of animals, including horses, have shown that the drug produces complete and effective anesthesia at dosages that are no more than half those needed when procaine is used. The following dosages have generally proved satisfactory in the horse and are therefore suggested as a guide:

For nerve block
(diagnosis of lameness, firing, pain relief in osteoarthritis, navicular disease)—3 to 15 mL

For epidural anesthesia
(animal standing)—5 to 20 mL

For intra-articular anesthesia
(removal of fracture chips, bone and bog spavin, arthritis)—10 to 15 mL

For infiltration
(alone or in combination with nerve block or intra-articular anesthesia)—as required

For anesthesia of the laryngeal mucosa prior to ventriculectomy
CARBOCAINE-V Sterile Aqueous Solution may be administered topically or by infiltration or by a combination of the two. For topical application, a total of 25 to 40 mL applied by spray (3 mL/application) is usually adequate. For infiltration, 20 to 50 mL will suffice.

HOW SUPPLIED
CARBOCAINE-V is available as 50 mL Multiple-Dose Vials.
Each mL contains 20 mg mepivacaine hydrochloride, 1 mg methylparaben as preservative, and sodium chloride for isotonicity. The pH was adjusted with sodium hydroxide or hydrochloric acid. Store at controlled room temperature 20° to 25° C (68° to 77° F). Contents should be used within 90 days after the first dose is removed.

NADA #100-703, Approved by FDA

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Made in Brazil

Revised: January 2013

054614ZOA&P
GEQ14005
Depo-Medrol®
methylprednisolone acetate  
sterile aqueous suspension  
20 mg per mL and 40 mg per mL  
For Use in Animals Only  

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.  

DESCRIPTION  
These preparations are recommended for intramuscular and intrasynovial injection in horses and 
dogs, and intramuscular injection in cats. DEPO-MEDROL Sterile Aqueous Suspension is available in 
two concentrations, 20 mg per mL and 40 mg per mL. Each mL of these preparations contains:  

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<tr>
<th>Component</th>
<th>Concentration</th>
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<tr>
<td>Methylprednisolone acetate</td>
<td>20 mg</td>
<td>40 mg</td>
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<tr>
<td>Polymethylgluconate</td>
<td>29.4 mg</td>
<td>58.8 mg</td>
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<tr>
<td>Sodium chloride</td>
<td>8.9 mg</td>
<td>8.7 mg</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium</td>
<td>0.196 mg</td>
<td>0.195 mg</td>
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<tr>
<td>chloride</td>
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When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.  

CLINICAL PHARMACOLOGY  
Metabolic and Hormonal Effects  
Methylprednisolone, an anti-inflammatory steroid synthesized and developed in the Research 
Laboratories of The Upjohn Company, is the 6-methyl derivative of prednisolone. Exceeding 
prednisolone in anti-inflammatory potency and having even less tendency than prednisolone to 
induce sodium and water retention, methylprednisolone offers the advantage over older corticoсте-
roids of affording an equally satisfactory anti-inflammatory effect with the use of lower doses and with 
an enhanced split between anti-inflammatory and mineralocorticoid activities. Estimates of the 
relative potencies of methylprednisolone and prednisolone range from 1.3 to 1.2, with an average of 
1.5. In anti-inflammatory activity, measured by the granuloma pouch assay, methylprednisolone 
is twice as active as prednisolone. In mineralocorticoid activity (ie, the capacity to induce retention 
of sodium and water in the adrenalectomized rat) methylprednisolone is slightly less active than 
prednisolone. During repeated dosing, the duration of the effect of methylprednisolone on intact 
dogs is appreciably longer for methylprednisolone than for prednisolone, the respective "half-life" value 
for the two steroids being 80.9 ± 7.5 minutes for methylprednisolone and 71.3 ± 1.7 minutes for 
prednisolone. While the effect of parenterally administered DEPO-MEDROL is prolonged, it has the same 
metabolic and anti-inflammatory actions as orally administered methylprednisolone acetate.  

INDICATIONS AND USAGE  
Musculoskeletal Conditions. As with other adrenal steroids, DEPO-MEDROL Sterile Aqueous 
Suspension has been found useful in alleviating the pain and lameness associated with acute 
localized inflammation or chronic and generalized arthritis. In some cases, pain and swelling 
resulting from traumatic injury may be successfully treated with methylprednisolone acetate. 
To treat rheumatoid arthritis, traumatic arthritis, osteoarthritis, periostitis, tendinitis, synovitis, 
tenosynovitis, bursitis, and myositis of dogs; traumatic arthritis, osteoarthrosis, and generalized 
arthritis of horses; and to treat the musculoskeletal conditions of some species of musculoskeletal 
conditions may be permanent, or symptoms may recur, depending on the cause and extent of 
statural de generation. Allergic Conditions. This preparation is especially beneficial in relieving pruritus and inflammation of allergic skin diseases, including bald dermatitis, dry eczema, urticaria, chonic asthma, pollen 
sensitivities and otitis externa in dogs; allergic dermatitis and moist and dry eczema in cats. Onset 
of relief may begin within a few hours to a few days following injection and may persist for 
about a few to six weeks. Symptoms may be expected to recur if the cause of the allergic reaction is still 
present, in which case retreatment may be indicated. In treating acute hypersensitivity reactions, 
such as anaphylactic shock, intravenous SULOL-DELTA-CORTEFE® Sterile Powder containing 
prednisolone sodium succinate is indicated.  

OVERALL INFLAMMATION  
In certain conditions where it is desired to reduce inflammation, vascularization, 
vascular permeability, and edema, corticosteroids are administered either intramuscularly, 
intrasynovially, or by intra-articular injection. Intra-articular injection of corticosteroids is 
particularly useful in treating certain infections. As supportive therapy, it improves the general 
state of the animal. The interval between repeated injections depends on the duration of relief 
that the animal is expected to experience. In treated joints, the number of injections made, 
and those like the sacroiliac joints, which are devoid of synovial space. Treatment failures are most 
marked when the following factors are present: (1) the disease is limited to a small group of 
more actively involved structures; (4) systemic therapy with other corticoids or corticotropin controls all but a few 
of the more actively involved structures; (4) systemic therapy with cortisone, hydrocortisone, or 
corronisol; (5) joints that have already been previously treated with corticosteroids; (2) the disease is limited to 
the extent of the underlying disease process, and whenever possible 
the disease is limited to one or a few peripheral structures 
other than those injected have been reported. No other systemic effects have been noted. However, it is possible that mild systemic effects may occur following intrasynovial administration, and this 
possibility is greater the larger the number of structures injected and the higher the total dose administered.  

PROCEDURE FOR INTRASYNOVIAL INJECTION  
The anaesthesia of the area to be injected should be achieved in order to ensure that the 
suprasternal and posterior auricular veins. The injection is made into the muscle mass, 
occurs, corticoid therapy should be discontinued and potassium chloride administered by continuous 
intravenous drip. While no sodium retention or potassium depletion has been observed at the doses recommended, 
animals receiving methylprednisolone acetate, as with all corticoids, should be under close 
admission and obtainable untoward effects. If symptoms of hypokalemia (hypokalemia) should occur, 
corticoid therapy should be discontinued and potassium chloride administered by continuous 
intraavenous drip. Since this drug lacks significant mineralocorticoid activity in usual therapeutic doses, it is 
May be hazardous. As with other corticoids, continued or prolonged use is discouraged.  

PRECAUTIONS  
DEPO-MEDROL Sterile Aqueous Suspension exerts an inhibitory influence on the mechanisms 
and the tissue changes associated with inflammation. Vascular permeability is decreased, exudation 
diminished, and migration of the inflammatory cells markedly inhibited. In addition, systemic mani-
festations such as fever and signs of toxemia may also be suppressed. While certain aspects of 
this alteration of the inflammatory reaction may be beneficial, the suppression of inflammation may 
masks the signs of infection and tend to facilitate spread of microorganisms. Hence, all patients 
receiving this drug should be watched for evidence of intercurrent infection. Should infection occur, 
it must be brought under control by the use of appropriate antibacterial measures, or administration 
of this preparation should be discontinued. However, in infections characterized by overwhelming 
toxaemia, the use of methylprednisolone acetate in conjunction with appropriate antibiotic therapy is 
effective in reducing mortality and morbidity. Without conjunt of an antibiotic to which the 
invader-organism is sensitive, injudicious use of the adrenal hormones in animals with infections 
cannot be recommended. As with other corticoids, treatment of infections is usually 
untoward effects. If symptoms of hypokalemia (hypokalemia) should occur, 
corticoid therapy should be discontinued and potassium chloride administered by continuous 
intraavenous drip. Since this drug lacks significant mineralocorticoid activity in usual therapeutic doses, it is 
likely to afford adequate support in states of acute adrenocortical insufficiency. For treatment of the 
latter, the parent adrenalocorticoids, hydrocortisone or cortisone, should be used.  

DOSE AND ADMINISTRATION  
INTRAMUSCULAR  
Following intramuscular injection of methylprednisolone acetate, a prolonged systemic effect 
results. The dose varies with the condition of the animal, the severity of the condition, and the animal's 
response to therapy.  

Dogs and Cats. The average intramuscular dose for dogs is 20 mg. In accordance with the size of 
the dog and severity of the condition, the dose may range from 5 mg to 40 mg, and even as high as 120 mg in extremely large breeds or dogs with severe involvement. The average intramuscular dose for cats is 10 mg with a range up to 20 mg. 
Injections may be made at weekly intervals or in accordance with the severity of the condition and 
clinical response.  

Horses. The usual intramuscular dose for horses is 200 mg repeated as necessary. For maintenance therapy in chronic conditions, initial doses should be reduced gradually until the 
appropriate effect (ie, individualized) dose is established. DEPO-MEDROL Tablets containing methylpred-
nyline may also be used for maintenance in dogs and cats, administered according to the 
recommended dose. When treatment is to be withdrawn after prolonged and intensive therapy, the dose should be reduced gradually. If signs of stress are associated with the condition being treated, the dose should be increased. If a 
rapid hormonal effect of maximum intensity is required, as in anaphylactic shock, the intravenous administration of methylprednisolone sodium succinate is indicated.  

INTRASYNOVIAL  
Methylprednisolone acetate, a slightly soluble ester of methylprednisolone, is capable of producing 
a more prolonged local anti-inflammatory effect than equimolar doses of hydrocortisone acetate. 
Following intrasynovial injection, relief from pain may be experienced within 12 to 24 hours. The 
duration of the effect is variable, but averages three to four weeks, with a range of one to five 
weeks. Injections of methylprednisolone acetate have been well tolerated. Intrasynovial (intra-articular) 
injections may occasionally result in an increased localized inflammatory response. 

Intrasynovial injection is recommended as an adjuvant to general therapeutic measures to effect 
epression of inflammation in one or a few peripheral structures when (1) the disease is limited to 
the extent of the underlying disease process; (4) systemic therapy with other corticoids or corticotropin controls all but a few 
of the more actively involved structures; (4) systemic therapy with cortisone, hydrocortisone, or 
corronisol; (5) joints that have already been previously treated with corticosteroids; (2) the disease is limited to 
the extent of the underlying disease process, and whenever possible 
the disease is limited to one or a few peripheral structures 
other than those injected have been reported. No other systemic effects have been noted. However, it is possible that mild systemic effects may occur following intrasynovial administration, and this 
possibility is greater the larger the number of structures injected and the higher the total dose administered.  

Storing at controlled room temperature 20° to 25° C (68° to 77° F). 
Contents should be used within 12 weeks after the first dose is removed.  

How Supplied  
DEPO-MEDROL Sterile Aqueous Suspension, 20 mg/mL is available in 20 mL vials, and 40 mg/mL is available in 5 mL vials. 
NADA 12-204, Approved by FDA  

Zoets  
Distributed by:  
Zoets Inc.  
Kalamazoo, MI 49007  
Revised: March 2013  
PAA034682AAP  
GEQ14006
When administered systemically in another study, however, various drugs dissolved in DMSO were bioavailable in higher concentrations than in plasma from the treated skin, with the exception of scopolamine hydrobromide. The absorption of phenobarbital dissolved in an aqueous solution of DMSO was impaired when administered orally to the rabbit. Absorption of the same drug in DMSO was improved in the dog, in which the compound was also shown to cross the blood—brain barrier. The absorption of phenobarbital was improved in dogs, but decreased as compared to saline control solutions. This was believed to be due to reduced diffusion through the dermis.

In vivo and in vitro methods demonstrated that DMSO enhanced the penetration of compounds in the skin of rats. The concentration of DMSO in the skin of DMSO treated and untreated groups was determined. The DMSO in this experiment was applied at a concentration of 100% for 3 hours. The concentration of DMSO in the skin was significantly higher in the DMSO treated group than in the untreated group. The concentration of DMSO in the skin increased with increasing concentrations of DMSO.

In a number of in vivo experiments (32, 36, 40) where DMSO was shown to be toxicologically in the treatment site, the concentration of DMSO in the skin was significantly higher in the DMSO treated group than in the untreated group. The concentration of DMSO in the skin increased with increasing concentrations of DMSO.

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DOMOSO Solution is recommended as a topical application to reduce acute swelling due to trauma.

ADMINISTRATION AND DOSAGE

DOMOSO Solution is administered topically to the skin over the affected area. Do not apply to any part of the mucous membranes, conjunctivae, or other mucosal surfaces. Do not permit the spray to come in contact with eyes. In small animals, spray pump should be initially held approximately 6 inches from the skin. In large animals, the spray pump should be adjusted to deliver a measured volume of 60 to 80 ml per application. If necessary, discontinue treatment for a minimum of 2 days.
(dormosedan®)

Sedative and Analgesic For Use in Horses Only

Stock Solution 10 mg/mL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Dormosedan® is a synthetic alpha-2 adrenoreceptor agonist with sedative and analgesic properties. Its chemical name is 40,4-dimethylaminoethyl(2-carboxyethyl)hydrazine hydrochloride and the generic name is detomidine hydrochloride. It is a white, crystalline, water-soluble substance having a molecular weight of 202.2. The molecular formula is C₁₇H₂₉N₄Cl.

CHEMICAL STRUCTURE:

![Chemical Structure Image]

Each mL of Dormosedan® contains 0.2 mg detomidine hydrochloride, 1.0 mg methylparaben, 5.5 mg sodium chloride, and water for injection, q.s.

CLINICAL PHARMACOLOGY: Dormosedan® is a non-competitive sedative and analgesic, in a potent, centrally-acting, alpha 2-receptor agonist which produces sedation and supine cranial analgesia which is dose dependent in its depth and duration. Prostration, falling, and a characteristic lowering of the head with reduced sensitivity to environmental stimuli (audible, etc.) are seen within minutes. A short period of recumbency is characteristic followed by immobility and a firm stance with front legs spread. The analgesic effect is most readily seen as an increase in the pain threshold at the body surface. Sensitivity to touch is little affected and in some cases may actually be enhanced.

With extensive administration, heart rate is markedly decreased, blood pressure is initially elevated, and then a steady decline to normal levels. A transient change in the conductivity of the cardiac muscle may occur as evidenced by partial atrioventricular (AV) or sinoatrial (SA) block. This change in the conductivity of the cardiac muscle may be prevented by IV administration of atropine at 0.3 to 0.1 mg/kg of body weight.

DOSAGE AND ADMINISTRATION: Dormosedan® is indicated for use in horses and is effective for brief minor surgical and diagnostic procedures, in horses during restraint and保定, and for sedation in horses, when it has been used successfully in the following:

- Calmative effect in horses; to provide relief from stress and anxiety;
- To facilitate bronchoscopy, bronchial lavage, and erosion or ulceration reduction; and to facilitate enterotomy,ways, and other non-sterile operations.

Additionally, an approved local anesthetic, when indicated, is recommended.

CONTRAINDICATIONS: Dormosedan® should not be used in horses with pre-existing AV or SA block or with severe cardiac insufficiency, emphysema, respiratory disease, or chronic asthmatic, bronchial, or pulmonary disease. Dormosedan® should also not be used in anesthetized or sedated horses as potentially fatal dysrhythmias may occur.

Information on the possible effects of detomidine hydrochloride in breeding horses is limited to controlled clinical reports; therefore, this drug is not recommended for use in breeding animals.

WARNINGS: Do not use in horses intended for human consumption. Not for horses used for food production.

HUMAN SAFETY INFORMATION: Care should be taken to ensure that detomidine hydrochloride is not inadvertently injected into safety studies have indicated that the drug is well absorbed when administered orally. Standard oral administration to rabbits using the proposed market concentration have shown that detomidine hydrochloride has no significant effects on rabbits or in vitro tests using tissues from the proposed market concentration of detomidine hydrochloride on intact and sham-operated rabbits have demonstrated that the drug is well tolerated by the skin and is apparently not absorbed orally. However, in accordance with prudent clinical practice, exposure of eyes or skin should be avoided and affected areas should be washed immediately if exposure occurs. As with all systemic drugs causing profound physiological effects, medical personnel should be available to administer emergency treatment in case of accidental self-injection.

PRECAUTIONS: Before administration, careful consideration should be given to administering Dormosedan® to horses approaching or in immediate or traumatic shock, in horses with advanced liver or kidney disease, or in horses under stress from extreme heat, cold, fatigue, or high altitude. Protective treated horses from external stimuli, extreme weather, and similar conditions. The horse should be observed closely the drug's effects and any adverse reactions should be treated promptly. If necessary, additional therapy should be administered as appropriate.
CONTRAINDICATIONS:
DORMOSEDAN GEL is contraindicated in horses with known hypersensitivity to detomidine. Intravenous potentiated sulfonamides should not be used in anesthetized or sedated horses as potentially fatal cardiovascular reactions may occur.

Do not use DORMOSEDAN GEL in horses with pre-existing atrioventricular (AV) or sino-atrial (SA) blocks, respiratory disease, or chronic renal failure.

WARNINGS:
For sublingual use in horses only. Do not use in horses intended for human consumption.

HUMAN WARNINGS: Not for human use. Keep out of the reach of children. Use impermeable gloves during drug administration and during procedures that require contact with the horse’s mouth. Following sublingual administration of detomidine oromucosal gel, drug concentrations up to 0.072 mg/mL were measured at 30 minutes post dose in equine saliva, equivalent to less than one percent of the original detomidine concentration in the gel. Mean drug concentrations fall to less than 0.010 mg/mL by 2 hours after drug administration, after which a slow decline occurs for several additional hours.

DORMOSEDAN GEL can be absorbed following direct exposure to skin, eyes, or mouth, and may cause irritation. Skin and mucosal contact with the product should be avoided. Use impermeable gloves at all times.

In case of accidental eye exposure, rinse abundantly with fresh water. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing.

Appropriate precautions should be taken while handling and using gel syringes. Accidental exposure could cause adverse reactions, including death, if not recognized and treated in a timely manner. Seek medical attention immediately but do not drive because sedation or changes in blood pressure may occur.

Individuals with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid exposure to this product.

Caution should be exercised when handling sedated horses. Handling or any other sudden stimuli, including noise, may cause a defense reaction in an animal that appears to be heavily sedated.

Rare cases of human use of detomidine products have been reported. DORMOSEDAN GEL should be managed to prevent the risk of diversion, through such measures as restriction of access and return to the outer carton for disposal. Remove gloves for occupational safety information. To report adverse reactions the material safety data sheet (MSDS) contains more detailed information. A field study is conducted to evaluate under field conditions, whether DORMOSEDAN GEL provided sufficient sedation and restraint in horses to successfully conduct procedures requiring administration of anesthetics or sedatives. On at least two occasions or at least one occasion, if any breed or sex were sedated to facilitate grooming (including cleaning of the prepuce), hoof care, floating teeth (manually), rectal palpation, intravaginal ultrasonography, or radiography. Horses were enrolled in the study if they were a yearling or older, in satisfactory body condition, and had a history of requiring sedation or other means of strong restraint to enable similar procedures to be carried out. Horses were randomly assigned to receive DORMOSEDAN GEL sublingually at 0.040 mg/kg or placebo gel.
After administration of treatment, each horse's level of sedation, degree of ataxia, heart rate and rhythm, and respiratory rate were assessed and measured to recovery. After an appropriate period of time elapsed to allow sedation to develop, a study veterinarian assessed and scored the ability to attempt and to complete the veterinary or husbandry procedure.

One hundred and twenty-nine DORMOSEDAN GEL-treated and 42 placebo-treated horses were included in the statistical analysis of effectiveness. Ninety-nine horses were excluded from the analysis due to failure to meet inclusion criteria or due to major protocol deviations. The veterinary or husbandry procedure was successfully completed for 88 of 129 DORMOSEDAN GEL-treated horses (76%) but only 3 of 42 placebo-treated horses (7%) (Table 3). The difference between the two treatments was statistically significant (p<0.0005).

Table 3: Treatment success rates (number of horses) by treatment group

<table>
<thead>
<tr>
<th>Ability to perform procedure score</th>
<th>DORMOSEDAN GEL</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=129</td>
<td>N=42</td>
</tr>
<tr>
<td>0</td>
<td>16</td>
<td>38</td>
</tr>
<tr>
<td>1</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>44</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>54</td>
<td>1</td>
</tr>
<tr>
<td>Success (score 2 or 3)</td>
<td>98</td>
<td>3</td>
</tr>
</tbody>
</table>

* 0: Poor – Strong resistance. 1: Fair. Moderate resistance. 2: Good. Some resistance, but the procedure could be performed. 3: Excellent. Procedure could be easily performed with insignificant resistance.

The following success rates with DORMOSEDAN GEL were recorded for electric clipping of hair (48%), cleaning the prepure (81%), manual floating of teeth (99%), hoof trimming or shoeing (96%), passage of a nasogastric tube or endoscope (85%), or radiography (74%). At 40 minutes post dosing, 94% of DORMOSEDAN GEL-treated horses showed minimal, moderate or marked sedation compared with 14% of the horses treated with placebo. All DORMOSEDAN GEL-treated horses had recovered from sedation by 240 minutes post treatment.

DORMOSEDAN GEL was correctly administered sublingually (beneath the tongue) in 97% of horses with mild or no objection.

**ANIMAL SAFETY:**

In a multiple dose target animal safety study, DORMOSEDAN GEL was administered on three consecutive days to 6 horses per treatment group at 0, 1, 3 and 5 times the recommended label dose of 0.040 mg/kg.

The recommended dose (1X) induced sedation. Head droop caused transient edema of the head area, nasal/oral discharge, and congestion of oral mucous membranes. Ataxia, sweating, and reversible penile prolapse were observed. Erythematous mucous membranes were seen at the area of dose application in 2/6 horses. Transient reductions were seen in heart rate, respiratory rate, and gut motility. Electrocardiography revealed increased incidences of vagally mediated arrhythmias (sinus arrhythmia, sinus block, 1st and 2nd degree atrioventricular block) as well as atrial or ventricular premature beats in the majority of horses. No clinical abnormalities were associated with the transient arrhythmias. Excessive or erratic urination were seen in isolated cases.

Similar treatment related findings were seen in horses receiving 3X and 5X doses. In most cases the incidence, severity, and duration of the findings were dose dependent. All findings in all dose groups were representative of the alpha2-adrenoceptor drugs used in horses.

**STORAGE INFORMATION:**

Store at controlled room temperature 20-25°C (68-77°F), with excursions permitted to 15-30°C (59-86°F), in the original package.

**HOW SUPPLIED:**

3.0 mL graduated oral dosing syringe, 7.6 mg/mL detomidine hydrochloride.

**DORMOSEDAN®** is a trademark of Orion Corporation.

**CLIENT INFORMATION SHEET FOR OWNER/HANDLER USE AND SAFETY:**

This summary contains important information about Dormosedan Gel. You should read this information before you administer Dormosedan Gel to your horse. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Dormosedan Gel.

What is Dormosedan Gel?

Dormosedan Gel is an oromucosal sedative containing detomidine hydrochloride. It is prescribed by veterinarians to allow procedures to be done in a tranquilized horse. Dormosedan Gel has not been shown to provide analgesia and should not be used for painful procedures.

How should the product be handled?

Always wear impermeable gloves when handling the dosing syringe with detomidine hydrochloride gel. Ask the veterinarian whether the gloves you plan to use are impermeable. For a minimum of 2 hours after administration, wear impermeable gloves when performing any tasks that require contact with the horse's mouth.

If you have or have had a history of cardiovascular disease (for example, hypertension or heart attack) take special precautions and avoid direct exposure to the dosing syringe. Do not come in contact with the mouth or any saliva of any horse that was treated with detomidine gel for a minimum of 2 hours.

What if I get the gel in my eyes or mouth?

Detomidine hydrochloride can be absorbed into your body after direct exposure through the eyes or mouth, and may cause irritation to these areas. In case of accidental eye exposure, flush with water for 15 minutes. If detomidine is exposed to the mucous membranes of the mouth, rinse without swallowing. In all cases of accidental exposure and possible ingestion, seek medical attention immediately. Accidental exposure could result in the drug affecting you, causing symptoms that include sleepiness, low blood pressure, and slower heart rate. DO NOT DRIVE because detomidine may cause you to feel drowsy or sleepy. Share the package information with your physician and tell the physician that the product contains an alpha2-adrenoceptor agonist.

What if I get the gel on my skin?

Detomidine hydrochloride can be absorbed into your body after direct exposure through the skin. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. Contact your physician if you have any questions or concerns.

The material safety data sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in humans or horses or to obtain an MSDS for this product call 1-888-963-8471.

How is Dormosedan Gel administered?

Dormosedan Gel should be given according to your veterinarian's instructions. Your veterinarian will tell you what amount of gel you should give to your horse. The appropriate dose is delivered beneath the tongue (sublingually) and is not meant to be swallowed. Make sure there is no food in the horse's mouth prior to administration.

The following drawing demonstrates correct administration of Dormosedan Gel beneath the tongue.

Following appropriate dosing of the gel, your horse should be kept in a quiet area until sedation is achieved. If after 40 minutes there is inadequate sedation and you suspect that the horse swallowed or spit out some of the gel, contact your prescribing veterinarian. Do not repeat the dose.

If you believe the correct dose of detomidine gel was administered but the horse remains inadequately sedated, contact the prescribing veterinarian. Do not repeat the dose.

Contact your prescribing veterinarian immediately if the dosing syringe fails during the administration of detomidine gel and you are unsure if too much or too little of the dose was given.

Do not re-use partial dosing syringes. Any unused product or waste material should be disposed of in accordance with local requirements and Federal prescription drug disposal guidelines. Ask your veterinarian for this information.

What should I expect after administering Dormosedan Gel?

Following appropriate dosing of the gel, your horse should be kept in a quiet area. As the drug takes effect, you will typically see the head lower and the front legs plant in a firm stance. This will usually take about 40 minutes. You may also notice slight swaying, sweating, salivation and slight muscle tremors. Be careful when handling sedated horses. Handling or any other sudden stimuli, including noise, may cause a defense reaction (for example, kicking) even in a horse that appears to be fully sedated. It may take up to 3-4 hours for the horse to recover from sedation. Withhold food and water until the horse has recovered.

What else should I know about Dormosedan Gel?

As with all prescribed medicines, Dormosedan Gel should only be given to the horse for which it was prescribed. This sheet provides a summary of information about Dormosedan Gel. If you have any questions or concerns about Dormosedan Gel or its effects on your horse or yourself, talk to your veterinarian.
**EXCEDE** (Ceftiofur Crystalline Free Acid)

For intramuscular injection in the horse.

**CAUTION**
Federal (FDA) law restricts this drug to use by or on the order of a licensed veterinarian. Federal Law prohibits extra-label use of this drug in cattle for disease prevention purposes, infections, frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

**DESCRIPTION**
**EXCEDE Sterile Suspension** is a ready-to-use formulation that contains the crystalline free acid of ceftiofur, which is a broad spectrum cephalosporin antibiotic active against Gram-positive and Gram-negative bacteria including β-lactamase-producing strains. Like other cephalosporins, ceftiofur is bactericidal in vivo, resulting in inhibition of cell wall synthesis.

Each mL of the ready-to-use sterile suspension contains ceftiofur crystalline free acid equivalent to 200 mg ceftiofur, in a caprylcicaprylic triglyceride (Miglyol®) and cottonseed oil based suspension.

**Figure 1. Structure of ceftiofur crystalline free acid:**

- **Chemical name of ceftiofur crystalline free acid:** 7-[[2-(2-amino-4-thiazolyl)-2-(methoxyimino)acetyl]amin]-3-[[2-(tamuranylmethyl)[3H]-1-oxo-5-
-1H-1-azonia-4,6(2H)-dione]-2-2-carboxylic acid

**INDICATION**
**EXCEDE Sterile Suspension** is indicated for the treatment of primary or secondary bacterial infections in horses caused by susceptible strains of Streptococcus equi subspp. zooepidemicus.

**DOSAGE AND ADMINISTRATION**
Shake well before using.

Administer two intramuscular injections to horses, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg). A maximum of 50 mL, or 60% of the total body weight, per injection site may be administered. Therapeutic drug concentrations are maintained for 6 days after the second injection (or a total of 10 days from the beginning of treatment) against *Streptococcus equi subspp. zooepidemicus*.

**Table 1. Dosing Schedule for EXCEDE Sterile Suspension.**

<table>
<thead>
<tr>
<th>Dose Volume (mL)</th>
<th>Weight (lb)</th>
<th>Dose Volume (mL)</th>
<th>Weight (lb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>1.0</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>1.0</td>
<td>2.0</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>2.0</td>
<td>4.0</td>
<td>10</td>
<td>40</td>
</tr>
<tr>
<td>2.0</td>
<td>6.0</td>
<td>10</td>
<td>60</td>
</tr>
<tr>
<td>2.0</td>
<td>8.0</td>
<td>10</td>
<td>80</td>
</tr>
<tr>
<td>2.0</td>
<td>10.0</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>2.0</td>
<td>12.0</td>
<td>10</td>
<td>120</td>
</tr>
<tr>
<td>2.0</td>
<td>14.0</td>
<td>10</td>
<td>140</td>
</tr>
<tr>
<td>2.0</td>
<td>16.0</td>
<td>10</td>
<td>160</td>
</tr>
</tbody>
</table>

**For intramuscular injection in the horse.**

**CONTRAINDICATIONS**
EXCEDE Sterile Suspension is contraindicated in horses with known allergy to ceftiofur or to ß-lactam (penicillins and cephalosporins) group antimicrobials. Due to the extended exposure in horses, the drug’s pharmacokinetic properties, adverse reactions may require prolonged care.

**WARNINGS**
Not for use in humans. For use in animals only. Keep this and all drugs out of reach of children. Consult a physician in case of accidental human exposure.

Do not use in horses intended for human consumption.

Penicillins and cephalosporins can cause allergic reactions in sensitized individuals. Topical exposure to such antimicrobials, including ceftiofur, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact with the product, the skin, eyes, mouth and clothing of individuals who may be exposed. Wear protective gloves. Persons with a known sensitivity to penicillins or cephalosporins should avoid exposure to this product. In the case of accidental eye exposure, flush with water for at least 15 minutes. In case of accidental skin or water exposure, wash with soap and water. Remove contaminated clothing.

**ANTIBACTERIAL WARNINGS**
Use of antibacterial drugs in the absence of a susceptible bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of development of drug-resistant bacteria.

**PRECAUTIONS**
Due to the extended exposure in horses, based on the drug’s pharmacokinetic properties, adverse reactions may require prolonged care.

**INDICATION**
Ceftiofur is a cephalosporin antibiotic. Like other β-lactam antimicrobials, ceftiofur exerts its inhibitory effect by interfering with bacterial cell wall synthesis. This interference is primarily due to its covalent binding to the peptidyl transferase center, transpeptidation and transglycosylation, which are essential for synthesis of the bacterial cell wall. Ceftiofur is not active against *Pseudomonas spp.* and *enterococci.*

The minimum inhibitory concentration (MIC) values for ceftiofur against label-claim pathogens isolated from lower respiratory tract infections in horses enrolled in 2007-2008 field effectiveness studies are presented in Table 4. All MICs were determined in accordance with the Clinical and Laboratory Standards Institute (CLSI) standards.

**Table 4. Activity of EXCEDE Against Pathogens Isolated from Horses Treated With EXCEDE in Field Studies in the U.S. During 2007-2008.**

<table>
<thead>
<tr>
<th>Disease Pathogen</th>
<th>Treatment</th>
<th># of Isolates</th>
<th>Time of Sample Collection</th>
<th>MIC90</th>
<th>MIC Range μg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Respiratory Tract Infection</td>
<td>Streptococcus equi subspp. zooepidemicus</td>
<td>36</td>
<td>Pre-Treatment</td>
<td>0.06</td>
<td>0.06-0.5</td>
</tr>
<tr>
<td></td>
<td>Staphylococcus aureus</td>
<td>23</td>
<td>Pre-Treatment</td>
<td>0.06</td>
<td>0.06-0.5</td>
</tr>
<tr>
<td></td>
<td><em>Clostridium septicum</em></td>
<td>10</td>
<td>Pre-Treatment</td>
<td>0.10</td>
<td>0.06-0.5</td>
</tr>
</tbody>
</table>

**EFFECTIVENESS**
A double masked, randomized, negative control, field study evaluated the effectiveness of two intramuscular doses of EXCEDE Sterile Suspension. Horses were treated for the treatment of lower respiratory infections caused by *Streptococcus equi subspp. zooepidemicus*. In this study, a total of 278 horses were treated with EXCEDE, and 69, 60% treated with saline injection; 59, 21% treated with NAXCEL® (ceftriaxone sodium 220 mg/mL); and 50, 18% placebo were included in the statistical analysis. Therapeutic success was characterized by no worsening of clinical signs at Day 5, clinical improvement at Day 5, resolution of the clinical signs by Day 15, and no recurrence of clinical signs by Day 15 after initial dosing. EXCEDE was superior to the saline control. Table 5 summarizes the clinical success rates obtained 15 and 25 days after the first dose.

**Table 5. Clinical success rates at Day 15 and 25.**

<table>
<thead>
<tr>
<th>Effectiveness Parameter</th>
<th>EXCEDE</th>
<th>Saline Control</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical success Day 15</td>
<td>73.53%</td>
<td>38.60%</td>
<td>0.003</td>
</tr>
<tr>
<td>Clinical success Day 25</td>
<td>69.12%</td>
<td>31.58%</td>
<td>0.002</td>
</tr>
</tbody>
</table>

**ANIMAL SAFETY**
Two studies, a target animal safety (TAS) study and a pharmacokinetic (PK) study (see CLINICAL PHARMACOLOGY section), were conducted to assess the safety of EXCEDE in the horse.

In the TAS study, healthy adult horses received 6 intramuscular (lateral neck) injections of EXCEDE Sterile Suspension at doses of either 3.0 (X), 6.0 (2X) or 9.0 (3X) mg/kg with a 4 day interval between each injection. In the PK study, there were no treatment related gastrointestinal findings for the three EXCEDE Sterile Suspension treatment groups. In the PK study, one horse treated with 6.0 mg/kg (2X) EXCEDE experienced a mild episode of colic the day after the second injection of EXCEDE. The horse recovered without treatment.

Injection site reactions were observed in both studies. In both studies, the largest injection volume administered was 30 mL per injection site. There were no observations of edema, necrosis or drainage at the injection sites in these studies. Firmness, swelling, and/or sensitivity were observed in all one injection site in all horses at the label dose. In the TAS study, injection site reaction measurements ranged from no measurable reaction to 16 x 33 x 1.5 cm. In the PK study, the largest area of edema associated with the injection site ranged from no detectable reaction to 4 x 3 x 0.8 cm area of edema. Injection site reactions developed within 2 days of injection and resolved within 1-18 days. In the PK study, 2 horses had small areas of firmness that had not resolved at the end of the study (21 days after injection). In both studies, a greater incidence of injection site reactions occurred after the second injection, and in several horses, swelling at the injection site resolved or occurred 1-5 days after injection.

In the PK study, several horses developed clinical signs consistent with foot pain (still in the front limbs when turned in tight circles, and increased pulses and heat to the front feet). One horse in the NAXCEL® group and one horse in the 6.0 mg/kg (2X) EXCEDE group were euthanized due to laminitis. Clinical signs of foot pain (coll limb and increased heat and pulses in feet) affected more horses, for a longer period of time, in all EXCEDE-treated groups as compared to NAXCEL and placebo treated groups. The study housing (multi-horse pens on concrete slab) and diet (time free choice alfalfa and grass mix and once a day pelleted) may have contributed to the development of foot pain. The prevalence and severity of these types of reactions in EXCEDE-treated horses may also contributed to the development of a stiff gait. A causal relationship between ceftiofur and foot pain could not be definitively determined.

**STORAGE CONDITIONS**
Keep refrigerated at room temperature 20° to 25°C (68° to 77°F). Shelf life before use. Contents should be used within 12 weeks after the first dose is removed.

**HOW SUPPLIED**
**EXCEDE** Sterile Suspension is available in the following package sizes:

- 100 mL vial
- 250 mL vial

**MADA #141-208. Approved by FDA**

**zoetis**

**Distributed by:** Zoetis Inc.

Kalamazoo, MI 49007

[www.EXCEDE.com](http://www.EXCEDE.com) or call 1-888-963-8471

Revised: November 2013

106429026A&P
Flunixamine Injectable Solution

50 mg/mL

Sterile Solution

Multi-Dose Vial

NOT FOR USE IN HUMANS

KEEP OUT OF REACH OF CHILDREN

For Intravesical or Intramuscular Use in Horses and for Intravesical Use in Beef and Dairy Cattle. Not for Use in Dry Dairy Cows and Veal Calves.

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Each milliliter of FLUNIXAMINE Injectable Solution contains flunixin meglumine equivalent to 50 mg flunixin, 0.1 mg edetate disodium, 2.2 mg sodium formaldehyde sulfoxylate, 4.0 mg diethanolamine, 207.2 mg propylene glycol, 5.0 mg phenol as preservative, hydrochloric acid, water for injection q.s.

PHARMACOLOGY

Flunixin meglumine is a potent, non-narcotic, nonsteroidal, analgesic agent with anti-inflammatory and antipyretic activity. It is significantly more potent than pentazocine, meperidine, and codeine as an analgesic in the rat yeast paw test.

Horse: Flunixin is four times as potent on a mg-per-mg basis as phenylbutazone as measured by the reduction in lameness and swelling in the horse. Plasma half-life in serum horse is 1.6 hours following a single dose of 1.1 mg/kg. Measurable amounts are detectable in horse plasma at 8 hours postinjection.

Cattle: Flunixin meglumine is a weak acid (pKa= 5.82) which exhibits a high degree of plasma protein binding (approximately 99%). However, free (unbound) drug appears to readily partition into body tissues (Vss predictions range from 297 to 782 mL/kg). Total body water is approximately equal to 570 mL/kg. Flunixin accumulation occurs primarily through biliary excretion. This may, at least in part, explain the presence of multiple peaks in the blood concentration/time profile following IV administration.

In healthy cattle, total body clearance has been reported to range from 90 to 151 mL/kg/hr. These studies also report a large discrepancy between the volume of distribution at steady state (Vss) and the volume of distribution associated with the terminal elimination phase (Vt). This discrepancy appears to be attributable to extended drug elimination from a deep compartment. The terminal half-life has been shown to vary from 3.14 to 8.12 hours.

Flunixin persists in inflammatory tissues and is associated with anti-inflammatory properties which extend well beyond the period associated with detectable plasma drug concentrations.

These observations account for the counterclockwise hysteresis associated with flunixin’s pharmacokinetic/pharmacodynamic relationships.

Therefore, prediction of drug concentrations based upon the estimated plasma terminal elimination half-life will likely underestimate both the duration of drug action and the concentration of drug remaining at the site of activity.

INDICATIONS

Horse: FLUNIXAMINE Injectable Solution is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic in the horse.

Cattle: FLUNIXAMINE Injectable Solution is indicated for the control of pyrexia associated with bovine respiratory disease, endotoxemia and acute bovine mastitis. FLUNIXAMINE Injectable Solution also is indicated for the control of inflammation in endotoxemia.

DOSE AND ADMINISTRATION

Horse:

The recommended dose for musculoskeletal disorders is 0.5 mg per pound (1 mL/100 lbs) of body weight once daily. Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days. Studies show onset of activity is within 2 hours. Peak response occurs between 12 and 18 hours and duration of activity is 24-36 hours.

The recommended dose for the alleviation of pain associated with equine colic is 0.5 mg per pound of body weight. Intravenous administration is recommended for prompt relief. Clinical studies show pain is alleviated in less than 15 minutes in many cases. Treatment may be repeated when signs of colic recur. During clinical studies approximately 10% of the horses required one or two additional treatments. The cause of colic should be determined and treated with concomitant therapy.

Cattle:

The recommended dose for control of pyrexia associated with bovine respiratory disease and endotoxemia and control of inflammation in endotoxemia is 1.1 to 2.2 mg/kg (0.5 to 1.0 mg/mL; 1 to 2 mL per 100 lbs) of body weight given once daily to 2.2 mg/kg (1 mL/2 lb; 1 mL per 100 lbs) of body weight given by slow intravenous administration either once a day as a single dose or divided into two doses administered at 12-hour intervals for up to 3 days. The total daily dose should not exceed 2.2 mg/kg (1 mL/2 lb; 1 mL per 100 lbs) of body weight given once by intravenous administration.

CONTRAINDICATIONS

Horse:

There are no known contraindications to this drug when used as directed. Intravascular injection should be avoided. Horses inadvertently injected intra-arterially can show adverse reactions. Signs can be axatia, incoordination, hyperventilation, hysteria, and muscle weakness. Signs are transient and disappear without antidotal medication within a few minutes. Do not use in horses showing hypersensitivity to flunixin meglumine.

Cattle:

NSAIDs inhibit production of prostaglandins which are important in signaling the initiation of parturition. The use of flunixin can delay parturition and prolong labor which may increase the risk of stillbirth. Do not use FLUNIXAMINE Injectable Solution within 48 hours of expected parturition. Do not use in animals showing hypersensitivity to flunixin meglumine. Use judiciously when renal impairment or gastric ulceration are suspected.

RESIDUE WARNINGS: Cattle must not be slaughtered for human consumption within 4 days of the last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Not for use in dry dairy cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Not for use in horses intended for food. Approved only for intravenous administration in cattle. Intramuscular administration has resulted in involuntary residues in the edible tissues of cattle sent to slaughter.

PRECAUTIONS

As a class, cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal and renal toxicity. Sensitivity to drug-associated adverse effects varies with the individual patient. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction.

Since many NSAIDs possess the potential to induce gastrointestinal ulceration, concomitant use of FLUNIXAMINE Injectable Solution with other anti-inflammatory drugs, such as other NSAIDs and corticosteroids, should be avoided or closely monitored.

Horse: The effect of FLUNIXAMINE Injectable Solution on pregnancy has not been determined. Studies to determine activity of FLUNIXAMINE Injectable Solution when administered concomitantly with other drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring adjunctive therapy.

Cattle: Do not use in bulls intended for breeding, as reproductive effects of FLUNIXAMINE Injectable Solution in these classes of cattle have not been investigated. NSAIDs are known to have potential effects on both parturition and the estrous cycle. There may be a delay in the onset of estrus if flunixin is administered during the prostaglandin phase of the estrous cycle. The effects of flunixin on imminent parturition have not been evaluated in a controlled study. NSAIDs are known to have the potential to delay parturition through a tocolytic effect. Do not exceed the recommended dose.

SAFETY

Horse: A 3-fold intramuscular dose of 1.5 mg/kg of body weight daily for 10 consecutive days was safe. No changes were observed in hematology, serum chemistry, or urinalysis values. Intravenous dosages of 0.5 mg/kg daily for 15 days; 1.5 mg/kg daily for 10 days; and 2.5 mg/kg daily for 5 days produced no changes in blood or urine parameters. No injection site irritation was observed following intramuscular injection of the 0.5 mg/kg recommended dose. Some irritation was observed following a 3-fold dose administered intramuscularly.

Cattle: No flunixin-related changes (adverse reactions) were noted in cattle administered a 1X (2.2 mg/kg, 1.0 mg/lb) dose for 9 days (three times the maximum clinical duration). Minimal toxicity manifested itself at moderately elevated doses (3X and 5X) when flunixin was administered daily for 9 days, with occasional findings of blood in the feces and/or urine. Discontinue use if hematuria or fecal blood are observed.

ADVERSE REACTIONS

In horses, isolated reports of local reactions following intramuscular injection, particularly in the neck, have been received. These include localized swelling, sweating, induration, and stiffness. In rare instances in horses, fatal or nonfatal clostridial infections or other infections have been reported in association with intramuscular use of flunixin meglumine. In horses and cattle, rare instances of anaphylactic-like reactions, some of which have been fatal, have been reported, primarily following intravenous use.

HOW SUPPLIED

FLUNIXAMINE Injectable Solution, 50 mg/mL, is available in 100 mL and 250 mL multi-dose vials. Store between 2° and 30°C (36° and 86°F). PROTECT FROM FREEZING.

REFERENCES


Manufactured by: Bimeda-MTC Animal Health Inc. Cambridge, ON Canada

Distributed by: Zoetis Inc. Kalamazo, MI 49007

Revised: March 2014

11952603A&P
HYLARTIN® V
sodium hyaluronate injection

10 mg/mL

Product Information

CAUTION:
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:
HYLARTIN® V is a sterile pyrogen-free solution of a highly purified, specific fraction of the sodium salt of hyaluronic acid extracted from rooster combs. HYLARTIN® V is supplied in disposable glass syringes, each of which contains 20 mg (10 mg/mL) of sodium hyaluronate in 2.0 mL physiological sodium chloride-phosphate buffer with a pH of 7.0-7.5.

CHEMISTRY:
Sodium hyaluronate is a high molecular weight polymer made up of repeating disaccharide units of N-acetylglucosamine and sodium glucuronate linked by beta 1-3 and beta 1-4 glycosidic bonds. HYLARTIN® V contains only traces of protein.

PHARMACOLOGY:
Sodium hyaluronate is a natural, physiological substance which occurs extracellularly in connective tissue in both animals and man and is chemically identical in different species. High concentrations (>0.2 mg/mL) of hyaluronate are found in the synovial fluid, the vitreous of the eye and the umbilical cord. Sodium hyaluronate is a normal component of connective tissue matrix and it is injected therapeutically only in compartments where it constitutes a normal component, specifically the joint cavity.

ANIMAL SAFETY:
Acute, sub-acute and chronic toxicity studies in mice, rats, rabbits, dogs, monkeys and horses have not demonstrated any significant adverse reactions or sensitization.

In an acute toxicity study in horses, HYLARTIN® V was injected intra-articularly at dosages corresponding to five times the recommended dose per animal (200 mg total). In a sub-acute study, horses were injected intra-articularly with the recommended dose per joint (20 mg) at weekly intervals for nine weeks. The results of both investigations showed that hematological and blood chemistry values remained within normal ranges. In mice, the intravenous LD 100 was found to be of the order of 50 mg/kg body weight.

There is always a potential immunological risk with repeated parenteral administration of biological material. However, as shown by Richter (1974), sodium hyaluronate, of both human and avian origin, did not produce any antibodies after repeated immunization, nor did intense stimulation of the immunization process by coupling of protein to the hyaluronate and simultaneous administration of Freund’s adjuvant give rise to antibodies.

CLINICAL STUDIES:
Clinical field trials with thoroughbred and standardbred race horses were undertaken at four separate clinics. A total of 252 joints were injected with HYLARTIN® V in these investigations. In one study, only horses which were conventional treatment failures were included and the overall improvement rate following HYLARTIN® V treatment approached 90 percent. In the other studies, the improvement rate surpassed this figure. In another case, electromyography was used to objectively show that HYLARTIN® V can improve the function of arthritic carpal and fetlock joints. HYLARTIN® V brought return to symmetry with respect to timing and duration of various angular motions of the joints. In cases where HYLARTIN® V was not able to achieve contralateral symmetry of the joint motion pattern, blocking of the joint with anesthetic also had no effect, indicating that most probably mechanical damage was responsible for the joint dysfunction.

INDICATIONS:
HYLARTIN® V, is indicated in the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

CONTRAINDICATIONS:
None known.

WARNING:
Do not use in horses intended for human consumption. HYLARTIN® V must not be administered intravascularly.

PRECAUTIONS:
Used or partially used syringes should be crushed and disposed of in an approved landfill.

ADVERSE REACTIONS:
The side effects observed in clinical trials were heat (15%), transient edema (12%), and pain (9%) around the treated joint. These side effects have been observed after intra-articular injection. Most of these reactions were of mild nature and in no case did they require the discontinuance of treatment. These reactions subsided in 24 to 48 hours. For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Zoetis Inc. at 1-888-963-8471.

DOSEAGE AND ADMINISTRATION:
2 mL (20 mg) of HYLARTIN® V given to horses intra-articularly in small and medium size joints (carpal, fetlock). In the treatment of larger joints (hock), the dosage is 4 mL (40 mg). The treatment may be repeated at weekly intervals for a total of three treatments.

HYLARTIN® V should be injected in horses intra-articularly under strict aseptic conditions. Effusion should be removed prior to injection. When performing the injections, care should be taken not to scratch the cartilage surface, as this may result in diffuse swelling lasting for 24 to 48 hours. This transient swelling, however, will have no effect on the ultimate clinical result. For best results, the horse should be given two days stall rest before gradually resuming normal activity.

STORAGE CONDITIONS:
Store at 2° to 8°C. The expiration date is stated on the package. Protect from freezing. Protect from light.

HOW SUPPLIED:
HYLARTIN® V, is supplied sterile in disposable glass syringes, each containing 20 mg (10 mg/mL) of sodium hyaluronate in 2.0 mL physiological sodium chloride-phosphate-buffer. Each mL contains:
Sodium hyaluronate 10.0 mg, sodium chloride 8.5 mg, disodium hydrogen phosphate dihydrate 0.28 mg, sodium dihydrogen phosphate hydrate 0.04 mg, water for injection USP q.s.

REFERENCE:
NADA 112-048, Approved by FDA
Made in Sweden by:
AMO Uppsala AB, Rapsgatan 7 Box 6406, SE-751 36 Uppsala, Sweden

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Revised: October 2014
52-0241-00A&P
**KETOFEN® (ketoprofen)**

Sterile Solution, 100 mg/mL

For intravenous use in horses only.

**CAUTION**

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION**

Ketoprofen is a non-steroidal anti-inflammatory agent of the propionic acid class that includes ibuprofen, naproxen and fenoprofen. Each mL of KETOFEN (ketoprofen) contains 100 mg of ketoprofen in an aqueous formulation containing: L-Arginine, 70 mg; citric acid (to adjust pH); benzyl alcohol, 0.025 g (as preservative). It is packaged in a multiple dose bottle.

**PHARMACOLOGY**

KETOFEN is a non-narcotic, non-steroidal anti-inflammatory agent with analgesic and antipyretic properties.

In horses, intravenous dosages of ketoprofen ranging from 0.5 to 1.5 mg/lb resulted in dosage dependent anti-inflammatory effects in the chronic adjuvant carpitis model as depicted in the following graph.

**MAXIMUM FLEXION**

(mean ± sem, n = 4)*

![Graph showing maximum flexion](image)

Additional studies using the same model in horses have shown that the effects of ketoprofen are maximal by 12 hours and still measurable at 24 hours after each dosage as depicted in the following graph.

**MAXIMUM FLEXION**

(mean ± sem, n = 6)*

![Graph showing maximum flexion](image)

*sem = standard error of the mean
n = number of animals

**TOXICITY**

Horses were found to tolerate ketoprofen given intravenously at dosages of 0, 1, 3 and 5 mg/lb once daily for 15 consecutive days (up to five times the recommended dosage for three times the usual duration) with no evidence of toxic effects. In clinical studies, intravenous injection of 1 mg/lb/day for five days resulted in no injection site irritation or other side effects.

At 15-fold overdose (15 mg/lb/day) for five days one of two horses developed severe laminitis, but no gross lesions or histologic changes were observed. The toxic effects observed in the horses given a 25-fold overdose (25 mg/lb/day) for five days included inappetence, depression, icterus, abdominal swelling and postmortem findings of gastritis, nephritis and hepatitis.

**INDICATION**

KETOFEN® (ketoprofen) is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

**ADMINISTRATION AND DOSAGE**

The recommended dosage is 1 mg/lb (1 mL/100 lbs) of body weight once daily. Treatment is administered by intravenous injection and may be repeated for up to five days. Onset of activity is within two hours with peak response by 12 hours.

**CONTRAINDICATIONS**

There are no known contraindications to this drug when used as directed. Intra-arterial injection should be avoided. Do not use in a horse if it has previously shown hypersensitivity to ketoprofen.

**CAUTION**

This product should not be used in breeding animals since the effects of KETOFEN on fertility, pregnancy or fetal health in horses have not been determined.

**PRECAUTIONS**

Studies to determine activity of KETOFEN when administered concomitantly with other drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring adjunctive therapy.

**WARNING**

Do not use in horses intended for human consumption.

**SIDE EFFECTS**

During investigational studies, no significant side effects were reported.

**HOW SUPPLIED**

KETOFEN (ketoprofen) Solution 100 mg/mL is available in 50 mL and 100 mL multidose bottles.

Store at controlled room temperature 20° to 25°C (68° to 77°F).

Distributed by: Zoetis Inc.

Kalamazoo, MI 49007

Revised: January 2013
Lutalyse® Injection (dinoprost injection)
5 mg dinoprost/mL as dinoprost tromethamine

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION
LUTALYSE® Injection (5 mg dinoprost/mL) is a sterile solution containing the naturally occurring prostaglandin F2 alpha; in the tromethamine salt. Each mL contains dinoprost tromethamine equivalent to 5 mg dinoprost: also, benzyl alcohol, 16.5 mg added as preservative. When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid. Dinoprost tromethamine is a white or slightly off-white crystalline powder that is readily soluble in water at room temperature in concentrations to at least 200 mg/mL.

INDICATIONS FOR USE
Cattle: LUTALYSE Injection is indicated as a luteolytic agent. LUTALYSE Injection is effective only in those cattle having a corpus luteum, i.e., those which ovulated at least five days prior to treatment.

Future reproductive performance of animals that are not cycling will be unaffected by injection of LUTALYSE Injection.

For estrus synchronization in beef cattle and non-lactating dairy heifers:
• For estrus synchronization in beef cattle and non-lactating dairy heifers
• For cows with an unruptured (silent) estrus in lactating dairy cows with a corpus luteum
• For treatment of pyometra (chronic endometritis) in cattle
• For corpora lutea in postpartum dairy heifers
• For postpartum therapy in dairy cattle

For abortion of feedlot and other non-lactating cattle
• For abortion of feedlot and other non-lactating cattle
• For use with FACTREL (gonadorelin injection) injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows
• For use with EAZI-BREED® CIDR® (progesterone intravaginal insert) Cattle Insert for synchronization of estrus in lactating dairy cows
• For use with EAZI-BREED® CIDR® (progesterone intravaginal insert) Cattle Insert for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first postpartum estrus in beef heifers

Mares:
• For controlled breeding (timed service) in mares
• For difficult-to-breed mares (clinically anestrous mares that have a corpus luteum)

Swine:
• For parturition induction in swine
• For estrus synchronization in swine

DOSE AND ADMINISTRATION
As with any multi-dose vial, practice aseptic techniques in withdrawing each dose to decrease the possibility of post-injection bacterial infections. Adequately clean and disinfect the vial stopper prior to entry with a sterile needle and syringe. Use only sterile needles, and use each needle only once.

No vial stopper should be entered more than 20 times. For this reason, the 100 mL bottle should only be used for cattle. The 30 mL bottle may be used for cattle, swine, or mares.

6. For use with EAZI-BREED™ CIDR® (progesterone intravaginal insert) Cattle Insert for Synchronization of Estrus in Lactating Dairy Cows:
   • Administer one EAZI-BREED CIDR Cattle Insert per animal and remove 7 days later (for example if administered on a Monday remove the following Monday).
   • Administer 5 mL LUTALYSE Injection at the time of removal of the EAZI-BREED CIDR Cattle Insert.
   • Observe animals for signs of estrus on Days 2 to 5 after removal of the EAZI-BREED CIDR Cattle Insert and inseminate animals found in estrus following normal herd practices.

7. For use with EAZI-BREED™ CIDR® (progesterone intravaginal insert) Cattle Insert for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first postpartum estrus in beef heifers:
   • Administer one EAZI-BREED CIDR Cattle Insert per animal for 7 days (for example, if administered on a Monday remove the following Monday).
   • Inject 5 mL LUTALYSE Injection (equivalent to 5 mg/mL dinoprost) 1 day prior to EAZI-BREED CIDR Cattle Insert removal, on Day 6 of the 7 day administration period.
   • Observe animals for signs of estrus on Days 1 to 3 after removal of the EAZI-BREED CIDR Cattle Insert and inseminate animals about 12 hours after onset of estrus.

Swine:
For Parturition Induction in Swine: For intramuscular use for parturition induction in swine.

LUTALYSE injection is used for parturition induction in swine when injected within 3 days of normal predicted farrowing. The response to treatment varies by individual animals with a mean interval from administration of 2 mL LUTALYSE Injection (10 mg dinoprost) to parturition of approximately 30 hours. This can be employed to control the timing of farrowing in sows and gilts in late gestation.

Management Considerations:
Several factors must be considered for the successful use of LUTALYSE Injection for parturition induction in swine. The product must be administered at a relatively short time (3 days prior to normal predicted farrowing) to prevent the sow from aborting and/or losing the piglet (which may result in increased piglet mortality). It is important that adequate records be maintained on (1) the average length of gestation period for the animals on a specific location, and (2) the breeding and projected farrowing dates for each animal. This information is essential to determine the appropriate time for administration of LUTALYSE Injection.

Mares: LUTALYSE Injection is indicated for its luteolytic effect in mares. Administer a single intramuscular injection of 1 mg per 100 lbs (45.5 kg) body weight which is usually 1 mL to 2 mL LUTALYSE Injection. This luteolytic effect can be utilized to control the timing of estrus in estrous cycling and clinically anestrous mares that have a corpus luteum in the following circumstances:

1. Controlling Time of Estrus of Estrous Cycling Mares: Mares treated with LUTALYSE Injection during diestrus (4 or more days after ovulation) will return to estrus within 2 to 4 days in most cases and ovulate 8 to 12 days after treatment. This procedure may be utilized as an aid to scheduling the use of stallions.

2. Difficult-to-Breed Mares: In extended diestrus there is failure to exhibit regular estrous cycles which is different from true anestrus. Many mares described as anestrous in late gestation have serum progesterone levels consistent with the presence of a functional corpus luteum. A proportion of “barren”, maiden, and lactating mares do not exhibit regular estrous cycles and may be in extended diestrus. Following abortion, early fetal death and resorption, or as a result of “pseudopenancy”, there may be serum progesterone levels consistent with a functional corpus luteum. Treatment of such mares with LUTALYSE Injection usually results in regression of the corpus luteum followed by estrus and/or ovulation. Treatment of “anestrous” mares which abort subsequent to 36 days of pregnancy may not result in return to estrus due to presence of functional endometrial cups.

WARNINGS AND PRECAUTIONS
User Safety: Not for human use. Keep out of the reach of children. Women of childbearing age, aromatherapists and persons with bronchial atopy and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and/or chorioamnionitis. Accidental spillage on the skin should be washed off immediately with soap and water.

To report suspected adverse events, for technical assistance or to obtain a copy of the Material Safety Data Sheet (MSDS) contact Zoetis Inc. at 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

Residue Warnings: No milk discard or pre-slaughter drug withdrawal period is required for labeled uses in cattle. No pre-slaughter drug withdrawal period is required for labeled uses in swine. Use of this product in excess of the approved dose may result in drug residues. Do not use in horses intended for human consumption.

Animal Safety Warnings: Severe localized cutaneous infections associated with injection of LUTALYSE Injection have been reported. In rare instances, such infections have resulted in death. Cattle administered a progestin would be expected to have a reduced clinical response to LUTALYSE Injection if administered in excess of the approved dose. Do not use in horses or other species unless abortion is desired. Cattle administered a progestin would be expected to have a reduced response to LUTALYSE Injection. Do not administer to sows and/or gilt prior to 3 days of normal

Below are three examples of treatment regimens for FTAI that fit within the dosage regimen framework described immediately above:

<table>
<thead>
<tr>
<th>Day 0 (Monday)</th>
<th>Example 1</th>
<th>Example 2</th>
<th>Example 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st FACTREL</td>
<td>1st FACTREL</td>
<td>1st FACTREL</td>
<td></td>
</tr>
</tbody>
</table>

| Day 7 (the following Monday) | LUTALYSE | LUTALYSE | LUTALYSE |

| Day 9 (Wednesday) | 2nd FACTREL + FTAI at 48 hours after LUTALYSE | 2nd FACTREL at 48 hours after LUTALYSE | 2nd FACTREL at 56 hours after LUTALYSE |

| Day 10 (Thursday) | FTAI 24 hours after 2nd FACTREL | FTAI 18 hours after 2nd FACTREL | FTAI 24 hours after 2nd FACTREL |
predicted farrowing as an increased number of stillbirths and postnatal mortality may result. In mares, LUTALYSE Injection is ineffective when administered prior to day-5 after ovulation. Mare pregnancy status should be determined prior to treatment since LUTALYSE Injection has been reported to induce abortion and parturition when sufficient doses were administered. Mares should not be treated if they suffer from either acute or subacute disorders of the vascular system, gastrointestinal tract, respiratory system, or reproductive tract.

ADVERSE REACTIONS

Cattle: Limited salivation has been reported in some instances.

Swine: These side effects were exema and pruritus, slight incoordination, nestling behavior, itching, urination, defecation, abdominal muscle spasm, tail movements, hyperpnea or dyspnea, increased vocalization, salivation, and at the 100 mg (10x) dose only, possible vomiting. These side effects are transitory, lasting from 10 minutes to 3 hours, and were not detrimental to the health of the animal.

Mares: The most frequently observed side effects are sweating and decreased rectal temperature. However, these have been transient in all cases observed and have not been detrimental to the animal. Other reactions seen have been increased heart rate, increased in respiratory rate, some abdominal discomfort, locomotor incoordination, and lying down. These effects are usually seen within 5 minutes of injection and disappear within one hour. Mares usually continue to eat during the period of expression of side effects. In a collection of several hundred mares treated with LUTALYSE Injection was reported but was not confirmed.

Contact Information: To report adverse reactions call Zoetis Inc. at 1-888-963-8471.

CLINICAL PHARMACOLOGY

General Biologic Activity: Prostaglandins occur in nearly all mammalian tissues. Prostaglandins, especially PGE’s and PGF’s, have been shown, in certain species, to 1) increase at time of parturition in amniotic fluid, maternal placenta, myometrium, and blood, 2) stimulate myometrial activity, and 3) to induce either abortion or parturition. Prostaglandins, especially PGF2α, have been shown to 1) increase in the uterus and blood to levels similar to levels achieved by exogenous administration which elicited luteolysis, 2) be capable of crossing from the uterine vein to the ovarian artery (sheep), 3) be related to luteolytic dose, and (4) be capable of regressing the corpus luteum of most mammalian species studied to date. Prostaglandins have been reported to result in release of pituitary tropic hormones. Data suggest prostaglandins, especially PGE’s and PGF’s, may be involved in the process of ovulation and gamete transport. Also PGF2α has been reported to cause increase in blood pressure, bronchoconstriction, and smooth muscle stimulation in certain species.

Metabolism: A number of metabolism studies have been done in laboratory animals. The metabolism of tritium labeled dinoprost (H PGF2 alpha) in the rat and in the monkey was similar. Although quantitative differences were observed, qualitatively similar metabolites were produced. A study demonstrated that equimolar doses of H PGF2 alpha Tham and H PGF2 alpha free acid administered intravenously to rats demonstrated no significant differences in blood concentration of dinoprost. An interesting observation in the above study was that the radioactive dose of H PGF2 alpha rapidly distributed in tissues and dissipated in tissues with almost the same curve as it did in the serum. The half-life of dinoprost in bovine blood has been reported to be on the order of minutes. A complete study on the distribution and decline of H PGF2 alpha Tham in the tissue of rats was well documented with the work done in the cow. Cattle serum collected during 24 hours after doses of 0 to 250 mg dinoprost have been assayed by RIA for dinoprost and the 15-keto metabolites. These data support previous reports that dinoprost has a half-life of minutes. Dinoprost is a natural prostaglandin. All systems associated with dinoprost metabolism exist in the body; therefore, no new metabolic, transport, excrity, binding or other systems need be established by the body to metabolize injected dinoprost.

TARGET ANIMAL SAFETY

Laboratory Animals: Dinoprost was non-tumorigenic in rats when administered orally at 1.25, 3.2, 10.0 and 20.0 mg dinoprost/kg/day from day 6-15 of gestation or when administered subcutaneously at 0.5 and 1.0 mg/kg/day on gestation days 6, 7 and 8 or 9, 10 and 11 or 12, 13 and 14. Dinoprost was non-tumorigenic in the rabbit when administered either subcutaneously at doses of 0.5 and 1.0 mg dinoprost/kg/day on gestation days 6, 7 and 8 or 9, 10 and 11 or 12, 13 and 14 or 15, 16 and 17 or orally at doses of 0.01, 0.1 and 1.0 mg dinoprost/kg/day on days 6-18 or 5.0 mg/kg/day on days 8-18 of gestation. A slight and marked embryo lethal effect was observed in dams given 1.0 and 5.0 mg dinoprost/kg/day respectively. This was due to the expected luteolytic properties of the drug. A 14-day continuous intravenous infusion study in rats at 20 mg PGF2α per kg body weight indicated prostaglandins of the F series could induce bone destruction. However, such bone changes were not observed in monkeys similarly administered LUTALYSE Injection at 15 mg dinoprost per kg body weight for 14 days.

Cattle: In cattle, evaluation was made of clinical observations, clinical chemistry, hematology, urinalysis, organ weights, and gross plus microscopic measurements following treatment with various doses up to 10 mg. The injection of 2 mg dinoprost caused a rise in rectal temperature in animals given 2 mg dinoprost subcutaneously. A study conducted with cattle. At luteolytic doses, dinoprost had no effect on pregnancy. If given to a pregnant cow, it may cause abortion; the dose required for abortion varies considerably with the stage of gestation. Induction of abortion in feedlot cattle at stages of gestation up to 100 days of gestation ranged between 26 and 84; 80% or more of the pregnant cattle were less than 150 days pregnant. One anaphylactic reaction of several hundred mares treated with LUTALYSE Injection was reported but was not confirmed.

Mares: Dinoprost tromethamine was administered to adult mares (weighting 320 to 485 kg; 2 to 20 years old), at the rates of 0, 100, 200, 400, and 800 mg per mare per day for 8 days. Route of administration for each dose group was both intramuscularly (2 mares) and subcutaneously (2 mares). All mares were detected in all treated groups for clinical (reduced sensitivity to pain; locomotor incoordination; hypergammaglobulinemia; sweating; hyperthermia; labored respiration), blood chemistry (elevated cholesterol, total bilirubin, LDH, and glucose), and hematology (decreased eosinophils, increased hemoglobin, hematocrit, and erythrocytes) measurements. The effects in the 100 mg dose, and to a lesser extent, the 200 mg dose groups were transient in nature, lasting for a few minutes to several hours. Mares did not appear to sustain adverse effects following termination of the side effects.

TARGET ANIMAL SAFETY

CATTLE: For Treatment of Pyometra (chronic endometritis) in Cattle: In studies conducted with LUTALYSE Injection, pyometra was defined as presence of a corpus luteum in the ovary and uterine horns containing fluid but not a conceptus based on palpation per rectum. Return to normal was defined as evacuation of fluid and return of the uterine horn size to 40mm or less based on palpation per rectum at 14 and 24 days. Most cattle that recovered in response to LUTALYSE Injection recovered within 14 days after injection. After 14 days, recovery rate of treated cattle was no different than that of non-treated cattle.

For Abortion of Feedlot and Other Non-Lactating Cattle: Commercial cattle were palpated per rectum for pregnancy in series six feedlots. The percent of pregnant cattle in each feedlot less than 100 days of gestation ranged between 26 and 84; 80% or more of the pregnant cattle were less than 150 days of gestation. The abortion rates following injection of LUTALYSE Injection increased with increasing doses up to about 25 mg. As examples, the abortion rates, over 7 feedlots on the dose titration study, were 22%, 50%, 71%, 90% and 98% for treatment with the 8, 16, 32, 64 and 128 mg dose groups, respectively. Average rectal temperature during the period of decreased temperature was on the order of 97.5 to 98.6, with the greatest decrease observed in the 10 mg dose group.

EFFECTIVENESS

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For use with FACTREL® (gonadorelin injection) Injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows: For a full description of the studies conducted for the use of FACTREL Injection and LUTALYSE Injection, please refer to the labeling for FACTREL Injection.

Mares: For Difficult-to-Breed Mares: In one study with 122 Standardbred and Thoroughbred mares in clinical anestruis for an average of 58 days and treated during the breeding season, behavioral estrus was detected in 81 percent at an average time of 3.7 days after injection with 5 mg LUTALYSE Injection; ovulation occurred an average of 7.0 days after treatment. Of those mares bred, 59% were pregnant following an average of 1.4 services during that estrus.

HOW SUPPLIED

LUTALYSE Injection is available in 30 and 100 mL vials.

STORAGE, HANDLING, AND DISPOSAL

Store at controlled room temperature 20° to 25°C (68° to 77°F). Protect from freezing.

NADA 108-901, Approved by FDA

Distributed by: Zoetis Inc.
Kalamazoo, MI 49007

Revised: August 2014

zoetis

30196801A&P
**Naxcel®**

**brand of cephalothin sodium**

sterile powder

For intramuscular and subcutaneous injection in cattle only. For intramuscular injection in swine, sheep, goats, and horses. For subcutaneous injection only in dogs, day-old chickens and day-old turkey pouls. This product may be used in livestock, swine, and poultry.

**CAUTION:** Federal (USA) law restrict this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle, swine, chickens, and turkeys for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

**DESCRIPTION**

Naxcel Sterile Powder contains the sodium salt of ceftiofur which is a broad spectrum cephalosporin antibiotic active against Gram-positive and Gram-negative bacteria including β-lactamase-producing strains. Like other cephalosporins, ceftiofur is bactericidal in vitro, resulting from inhibition of cell wall synthesis.

Each mL of the reconstituted drug contains ceftiofur sodium equivalent to 50 mg ceftiofur. The pH was adjusted with sodium hydroxide and mono-basic potassium phosphate.

**Chemical Structure of Cefioturum Sodium**

5-[[3-cyano-4-fluorophenyl][2-chloro-1-(cyclohexylmethyl)propionyl]amino]-2-(1H-tetrazol-5-yl)-1,3,4-thiazole-3-carbothioic acid

**RECONSTITUTION OF THE STERILE POWDER**

Naxcel Sterile Powder should be reconstituted as follows:

1 gram vial—Reconstitute Sterile Water for Injection. Each mL of the resulting solution contains ceftiofur sodium equivalent to 50 mg ceftiofur.

4 gram vial—Reconstitute with 80 mL Sterile Water for Injection. Each mL of the resulting solution contains ceftiofur sodium equivalent to 50 mg ceftiofur.

Shake thoroughly prior to use.

**INDICATIONS**

**Cattle**

Naxcel Sterile Powder is indicated for treatment of bovine respiratory disease (shipping fever, pneumonia) associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni. Naxcel Sterile Powder is also indicated for the treatment of extended streptococcal and clostridial infections (foul milk, pododermatitis) associated with Fusobacterium necrophorum and Bacteroides melaninogenicus.

**Swine**

Naxcel Sterile Powder is indicated for treatment/control of swine respiratory disease (swine bacterial pneumonia) associated with *Mannheimia haemolytica* and *Actinobacillus pleuropneumoniae*.

**Goats**

Naxcel Sterile Powder is indicated for treatment of caprine respiratory disease (gassous pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

**Horses**

Naxcel Sterile Powder is indicated for treatment of caprine respiratory disease (gassous pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

**Day-Old Chicks**

Naxcel Sterile Powder is indicated for the treatment of canine urinary tract infections associated with *Escherichia coli* and *Proteus mirabilis*.

**Day-Old Turkey Pouls**

Naxcel Sterile Powder is indicated for the control of early mortality, associated with *E. coli* or other organisms susceptible to ceftiofur, in day-old turkey pouls.

**DOSEAGE AND ADMINISTRATION**

**Cattle**

Administer to cattle by intramuscular or subcutaneous injection at the dosage of 0.5 to 1.0 mg cepftiofur per pound (1.1 to 2.2 mg/kg) of body weight (1.2 mL reconstituted sterile solution per 100 lb body weight). Treatment should be repeated at 24-hour intervals for a total of three consecutive days. Additional treatments may be given on days four and five for animals which do not show a satisfactory response (not recovered) after the initial three treatments. Selection of dosage (0.5 to 1.0 mg/kg) should be based on the practitioner’s judgement of severity of disease (i.e., extent of elevated body temperature, depressed physical appearance, increased respiratory rate, coughing and/or loss of appetite). Pharmacokinetic data indicates that a single dose of 1 mg/kg is more rapid in lactating does. For lactating does, the high end of the dose range is recommended.

**Horses**

Administer to horses by intramuscular injection at the dosage of 1.0 to 2.0 mg cepftiofur per pound (2.2 to 4.4 mg/kg) of body weight (4 mL reconstituted sterile solution per 100 lb body weight). A minimum of 10 mL may be administered per injection site. Treatment should be repeated at 24-hour intervals for a total of three consecutive days. In horses, 48 hours after clinical signs have disappeared and should not exceed 10 days.

**Dogs**

Administer to dogs by subcutaneous injection at the dosage of 0.5 to 0.0 mg cepftiofur per pound (2.2 to 4.4 mg/kg) of body weight (0.6 mL reconstituted sterile solution per 100 lb body weight). Selection of dosage should be based on the practitioner’s judgement of severity of disease. For dogs, 48 hours after clinical signs have disappeared and should not exceed 10 days.

**ADVERSE REACTIONS**

Side effects of ceftiofur may result in some immediate and transient local pain to the animal.

**CLINICAL MICROBIOLOGY**

Summary of MICs of ceftiofur are presented in Tables 1 and 2. Testing followed Clinical and Laboratory Standards Institute (CLSI) Guidelines.
On the pharmacokinetic studies of ceftiofur in swine and cattle after a single intramuscular injection of 10.0 or 25.0 mg/kg body weight. A report of “Susceptible” indicates that the pathogen is likely to be inhibited in any of the treatment groups.

In a 15-day toxicity study in sheep, three wether and three ewe lambs were intramuscularly administered formulated ceftiofur at 0 (vehicle control), 1.36 to 2.27 mg/kg body weight. Day-Old Turkeys

Day-Old Chicks

An acute toxicity study of ceftiofur in day-old chicks revealed an acute LD₅₀ for 100 mg/kg of body weight. Treatment on day 1 was followed by 6 days of observation; body weight was determined on days 1, 4, and 7; and selected hematological parameters on day 4. No meaningful differences were noted among the treated and control groups of chicks for the parameters evaluated. Histopathologic evaluation of all deaths and chicks surviving to terminal did not reveal a target organ or tissue of potential toxicity of ceftiofur when administered at up to 200 mg/kg (100 µg/g) the intended highest use dosage.

Day-Old Poultry

In an acute toxicity study of ceftiofur in day-old turkey pouls, a total of 30 male and 30 female pouls were each administered single subcutaneous injections of 10, 100, or 1,000 µg/kg body weight. Treatment on day 1 was followed by 6 days of observation; body weight was determined on days 1, 4, and 7; and selected hematological parameters on day 4. No meaningful differences were noted among the treated and control groups of chicks for the parameters evaluated. Histopathologic evaluation of all deaths and chicks surviving to terminal did not reveal a target organ or tissue of potential toxicity of ceftiofur when administered at up to 500 µg/kg (250 µg/g) the highest use dosage. Tissue Residue Depletion

Cattle

A radiolabeled residue metabolism study established tolerances for ceftiofur residues in cattle kidney, liver and muscle. These tolerances of ceftiofur residues are 0.4 ppm in kidney, 2.0 ppm in liver, 1.0 ppm in muscle, and 0.1 ppm in milk.

A pivotal tissue residue decline study was conducted in cattle. In this study, cattle received an intramuscular injection of 1.0 mg of ceftiofur per kg body weight (2.2 mg/kg per kg body weight) for five consecutive days. Cattle residues in tissues were less than the tolerances for ceftiofur residues in tissues such as kidney, liver, and muscle by 4 days after dosing. These data collectively support a 4-day pre-slaughter withdrawal period in cattle when used according to label directions.

Swine

A radiolabeled residue metabolism study established tolerances for ceftiofur residues in swine kidney, liver, and muscle. These tolerances of ceftiofur residues are 0.25 ppm in kidney, 3.0 ppm in liver and 0.2 ppm in muscle.

A pivotal tissue residue decline study was conducted in swine. In this study, pigs received intramuscular injections of 100, 400 or 800 mg/kg body weight. Injection on day 1 was followed by 6 days of observation; body weight was determined on days 1, 4, and 7; and selected hematological parameters on day 4. No meaningful differences were noted among the treated and control groups of pigs for the parameters evaluated. Histopathologic evaluation of all deaths and pigs surviving to terminal did not reveal a target organ or tissue of potential toxicity of ceftiofur when administered at up to 200 mg/kg (100 µg/g) the intended highest use dosage.

STORAGE CONDITIONS

Store unmanufactured product at controlled room temperature 20° to 25°C (68° to 77°F).

Store reconstituted product either in a refrigerator 2° to 8°C (36° to 46°F) for up to 7 days or at controlled room temperature 20° to 25°C (68° to 77°F) for up to 12 hours.

Protect from light. Color of the cake may vary from off-white to a tan color. Color does not affect potency.

ONE-TIME SALVAGE PROCEDURE FOR RECONSTITUTED PRODUCT

At the end of the 7-day refrigeration or 12-hour room temperature storage period following reconstitution, any remaining reconstituted cake product may be frozen for up to 8 weeks without loss in potency or other chemical properties.

This is a one-time only salvage procedure for the remaining product. To use this salvaged product at any time during the 8-week storage period, hold the vial under warm running water, gently swirling the container to accelerate thawing, or allow the frozen material to thaw at room temperature. Rapid freezing or thawing may result in vial breakage. Any product not used immediately upon thawing should be discarded.

HOW SUPPLIED

NAXCEL Sterile Powder is available in the following package sizes: 1 gram vial 4 gram vial


zoeTis

Distributed by: Zoetis Inc.
KalamaZoo, Ml 48007

Revised: January 2014

30146300&N

References

Kalamazoo, MI 49007

Horses

In a study of horses, received a single intramuscular injection of either 0.1 mg/kg body weight (saline control), 0.5 mg/kg (50 mg/ml), 1.0 mg/kg (100 mg/ml) or 2.0 mg/kg (200 mg/ml) of aqueous suspension of ceftiofur sodium for 30 or 31 days. Cattle was well tolerated when administered intramuscularly to male and female horses at doses of up to 0.5 mg/kg for 30 or 31 days. No clinical evidence of irritation was noted at any dose. The drug-related changes detected in this study were limited to a transient decrease in food consumption in horses receiving 3.0 or 5.0 mg/kg ceftiofur sodium, and general mild skeletal muscle irritation at the injection sites which resolved by regeneration of muscle fibers.

In a tolerance study, horses received a single daily intramuscular injection of 10.0 or 25.0 mg/kg body weight (saline control) for 15 days. This study demonstrates that formulated ceftiofur has a wide margin of safety in cattle.

In a safety/toxicity study 5 lactating does, 5 dry does, and 5 wethers were intramuscularly administered formulated ceftiofur for 15 days. This study indicates that formulated ceftiofur is well tolerated and has a wide margin of safety in goats.

In a safety/toxicity study 5 lactating does, 5 dry does, and 5 wethers were formulated ceftiofur by the intramuscular route with 11 mg/gram for 15 days. This study confirms the observed recommended dose for 3 times the maximum recommended dose of 4 days of treatment. There were no adverse systemic effects indicating that formulated ceftiofur is well tolerated and has a wide margin of safety in sheep.

In a safety/toxicity study 5 lactating does, 5 dry does, and 5 wethers were formulated ceftiofur by the intramuscular route with 1 mg/gram for 11 mg/gram for 15 days. This study confirms the observed recommended dose for 3 times the maximum recommended dose of 4 days of treatment. There were no adverse systemic effects indicating that formulated ceftiofur is well tolerated and has a wide margin of safety in sheep.

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Predef® 2X
isoflupredone acetate
Sterile Aqueous Suspension
For Intramuscular or Intrasynovial Use Only
FOR USE IN ANIMALS ONLY

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION
Each mL of PREDEF 2X Sterile Aqueous Suspension contains 2 mg of isoflupredone acetate; also 4.5 mg sodium citrate hydrate; 120 mg polyethylene glycol 3350; 1 mg povidone; 0.201 mg myristyl-gamma-picolinium chloride added as preservative. When necessary, pH was adjusted with hydrochloric acid and/or sodium hydroxide. It is for intramuscular or intrasynovial injection in animals and is indicated in situations requiring glucocorticoid therapy and/or supportive effect.

Metabolic and Hormonal Effects
PREDEF 2X, a potent corticosteroid, has greater glucocorticoid activity than an equal quantity of prednisolone.
The glucocorticoid activity is borne out by its hyperglycemic effect in both normal and ketotic cattle.

INDICATIONS

Bovine Ketosis. PREDEF 2X Sterile Aqueous Suspension, by its glucocorticoid and glycogen deposition activity, is an effective and valuable hormone-endocrine and metabolic imbalance of primary bovine ketosis. The stresses of parturition and high milk production predispose the dairy cow to this condition. This adrenal steroid causes a prompt physiological effect, with blood glucose levels returning to normal or above normal within 8 to 24 hours following injection. There is a decrease in circulating eosinophils, followed by a reduction in blood and urine ketones. Usually the general attitude of the cow is much improved, appetite returns, and milk production rises to previous levels within 3 to 5 days. In secondary bovine ketosis, where the condition is complicated by pneumonia, mastitis, endometritis, traumatic gastritis, etc, PREDEF 2X should be used concurrently with proper local and parenteral antibacterial therapy, infusion solutions, and other accepted treatments for the primary conditions.

Musculoskeletal Conditions. As with other adrenal steroids, this preparation is found useful in alleviating the pain and lameness associated with generalized and acute localized arthritic conditions in large animals. PREDEF 2X has been used successfully to treat laminitis, rheumatoid and traumatic arthritis, osteoarthritis, periostitis, tendinitis, tenosynovitis, bursitis, and myositis. Generalized muscular soreness, stiffness, depression, and anorexia resulting from overwork, shipping, unusual physical exertion, etc, respond promptly. Remission of symptoms may be permanent, or symptoms may recur, depending on the cause and extent of structural degeneration.

Allergic Reactions. PREDEF 2X is especially beneficial in treating acute hypersensitivity reactions resulting from treatment with a sensitizing drug or exposure to other allergic agents. Usual manifestations are anaphylactoid reactions and urticaria. Less severe allergic manifestations, such as atopic dermatitis, urticaria, serous and conjunctival edema, may also be treated. Response is usually rapid and complete, although in severe cases with extensive lesions, more prolonged adrenocorticoid therapy and other appropriate treatment may be indicated.

Overwhelming Infections with Severe Toxicity. In animals moribund from overwhelmingly severe infections for which specific antibacterial therapy is available (eg, critical pneumonia, peritonitis, endometritis, septic mastitis), intensive PREDEF 2X therapy may aid in correcting the circulatory defect by combating the responsible inflammatory changes, thereby permitting the antibiotic agent to exert its full effect. As supportive therapy, this steroid combats the stress and improves the general attitude of the animal being treated. All necessary procedures for the establishment of a bacterial diagnosis should be carried out whenever possible before institution of therapy. PREDEF 2X Sterile Aqueous Suspension therapy in the presence of infection should be administered for the shortest possible time compatible with maintenance of an adequate response, and antibiotic therapy should be continued for at least three days after the hormone has been withdrawn. Combined hormone and antibacterial therapy does not obviate the need for indicated surgical treatment.

Shock. PREDEF 2X is indicated in adrenal failure and shocklike states occurring in association with severe injury or other trauma, emergency surgery, anaphylactoid reactions, and elective surgery in poor surgical risks. It is recommended as an adjuvant to standard methods of combating shock, including use of plasma expanders. Because of interrelated physiologic activities, beneficial effects may not be exhibited until all such procedures have been employed.

Other Indications. Exhaustion following surgery or dystocia, retained placenta, inflammatory ocular conditions, snakebite, and other stress conditions are also indications for use. Its employment in the treatment of these conditions is recommended as a supportive measure to standard procedures and time-honored treatments will give comfort to the animal and hasten complete recovery.

PREDEF 2X has been found useful as supportive therapy in the treatment of the stress associated with parturient paresis ie, milk fever. It should be given intramuscularly, before or after the administration of the calcium infusion solutions commonly employed in treating the disease. PREDEF 2X is not to be added to the infusion solutions.

WARNINGS

Animals intended for human consumption should not be slaughtered within 7 days of last treatment. Do not use in horses intended for human consumption. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Not for human use.

Clinical and experimental data have demonstrated that corticosteroids administered orally, as with all other animals, may cause slight uterine contractions in the first or under parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

PRECAUTIONS

PREDEF 2X Sterile Aqueous Suspension exerts an inhibitory influence on the mechanisms and the tissue changes associated with inflammation. Vascular permeability is decreased, exudation diminished, and migration of the inflammatory cells markedly inhibited. In addition, systemic manifestations such as fever and signs of toxemia may also be suppressed. While in certain aspects of this alteration of the inflammatory reaction may be beneficial, the suppression of inflammation may mask the signs of infection and tend to facilitate spread of microorganisms. However, in infections characterized by overwhelming toxicity, PREDEF 2X therapy in conjunction with appropriate antibacterial therapy is effective in reducing mortality and morbidity. Without concurrent use of an antibiotic to which the invader-organism is sensitive, injudicious use of the adrenal hormones in animals with infections can be hazardous. As with other corticoids, continued or prolonged use is discouraged.

While no sodium retention nor potassium depletion has been observed at the doses recommended in animals receiving 9-fluoro-11β,17α,21-trihydroxy-11,20-pregnadiene-3,20-dione, sodium chloride should be given concurrently or close observation for possible untoward effects. If symptoms of hypokalemia should occur, corticoid therapy should be discontinued and 5% solution of potassium chloride administered by continuous intravenous drip.

DOSAGE AND ADMINISTRATION

PREDEF 2X Sterile Aqueous Suspension is administered by deep intramuscular injection for systemic effect, or into joint cavity, tendon sheath, or bursa for local effect.

Cattle. The usual intramuscular dose for cattle is 10 to 20 mg, according to the size of the animal and severity of the condition. This dose may be repeated in 12 to 24 hours if indicated.

Ketosis studies have demonstrated that relatively high initial doses of corticoids produce a more prompt recovery with a lower incidence of relapse than when relatively low doses are used, even when these are repeated. Response of ketosis to PREDEF 2X therapy parallels that derived with prednisolone. PREDEF 2X is 10 times more glucocorticoid than prednisolone. Thus, 10 mg of isoflupredone acetate therapeutically equals 100 mg of prednisolone.

In the event of poor response or relapse, diagnosis should be reconfirmed by re-examining the animal for complications (ie, pneumonia, mastitis, traumatic gastritis, mastitis). Horses. The usual intramuscular dose for horses is 5 to 20 mg repeated as necessary. The usual intrasynovial dose in joint inflammation, tendinitis, or bursitis is 5 to 20 mg or more, depending on the size of the cavity to be injected.

Swine. The usual intramuscular dose for swine is 5 mg for a 300 pound animal. The dose for larger or smaller pigs is proportional to the weight of the animal.

HOW SUPPLIED
PREDEF 2X Sterile Aqueous Suspension, 2 mg per mL, is available in 100 mL vials. Store at controlled room temperature 20° to 25° C (68° to 77° F).

zoetis

Zoetis Inc.
Kalamazoo, MI 49007

Revised: March 2013

PAA036089A&P
GCE14017
Strongid® T
(pyrantel pamoate)

Equine Anthelmintic Suspension

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION:** Strongid T is a suspension of pyrantel pamoate in a palatable caramel-flavored vehicle. Each mL contains 50 mg of pyrantel base as pyrantel pamoate. Pyrantel pamoate is a compound belonging to a family classified chemically as tetrahydropyrimidines. It is a yellow, water-insoluble crystalline salt of the tetrahydropyrimidine base and pamoic acid containing 34.7% base activity. The chemical structure and name are given below:

\[
(E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl) vinyl] pyrimidine
4,4'-methylenebis[3-hydroxy-2-naphthoate] (1:1)
\]

**INDICATIONS AND USAGE:** For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.

**CONTRAINDICATIONS:** It is recommended that severely debilitated animals not be treated with this preparation.

**WARNINGS:** Do not use in horses intended for human consumption. Keep out of reach of children.

**PRECAUTION:** This product is a suspension and as such will separate. To insure uniform resuspension and to achieve proper dosage, it is extremely important that the product be shaken and stirred thoroughly before every use.

**DOSAGE AND ADMINISTRATION:** Administer 3 mg pyrantel base per lb of body weight (6 mL Strongid T per 100 lb of body weight). For maximum control of parasitism, it is recommended that foals (2–8 months of age) be dosed every 4 weeks. To minimize potential hazard that the mare may pose to the foal, she should be treated 1 month prior to anticipated foaling date followed by retreatment 10 days to 2 weeks after birth of foal. Horses over 8 months of age should be routinely dosed every 6 weeks.

**Directions for use:** Strongid T may be administered by means of a stomach tube, dose syringe or by mixing into the feed.

**Stomach Tube:** Measure the appropriate dosage of Strongid T and mix in the desired quantity of water. Protect drench from direct sunlight and administer to the animal immediately following mixing. Do not attempt to store diluted suspension.

Strongid T is inactive against the common horse bot (*Gasterophilus spp.*) However, Strongid T may be administered concurrently with carbon disulfide observing the usual precautions with carbon disulfide.

**Dose Syringe:** Draw the appropriate dosage of Strongid T into a dose syringe and administer to the animal. Do not expose Strongid T to direct sunlight.

**Feed:** Mix the appropriate dosage of Strongid T in the normal grain ration. Fasting of animals prior to or following treatment is not required.

**Efficacy:** Critical (worm-count) studies in horses demonstrated that Strongid T administered at the recommended dosage was efficacious against mature infections of *Strongylus vulgaris* (>90%), *S. edentatus* (69%), *S. equinus* (>90%), *Oxyuris equi* (81%), *Parascaris equorum* (>90%), and small strongyles (90%).

**SAFETY:** Strongid T is well tolerated by horses and ponies of all ages. No adverse drug response was observed when dose rates up to 60 mg of pyrantel base per lb of body weight were administered by stomach tube nor when 3 mg base per lb was given by intratracheal injection. The reproductive performance of pregnant mares and stud horses dosed with Strongid T has not been affected.

**RECOMMENDED STORAGE:** Store below 30°C (86°F).

**HOW SUPPLIED:** Strongid T is supplied in 1 quart (946 mL) bottles.

NADA #91-739, Approved by FDA

zoetis
Distributed by: Zoetis Inc.
Kalamazoo, MI 49007

13911800A&P
Revised: January 2013
Printed in USA
STR14002
**Acute Equine Studies**

Rapid intravenous administration of butorphanol at a dosage of 2 mg/kg (20 times the recommended dosage) to a previously unmedicated horse resulted in a brief episode of inability to stand, muscle fasciculation, a convulsive seizure of 6 seconds duration and recovery within three minutes. The same dosage administered after 10 successive daily 1 mg/kg dosages of butorphanol resulted only in transient sedative effects. During the 10-day course of administration at 1 mg/kg (10 times the recommended use level) in two horses, the only detectable drug effects were transient behavioral changes typical of narcotic agonist activity. These included muscle fasciculation about the head and neck, dysphoria, lateral nystagmus, ataxia and salivation. Repeated administration of butorphanol at 1 mg/kg (10 times the recommended dose) every four hours for 48 hours caused constipation in one of two horses.

**Subacute Equine Studies**

Horses were found to tolerate butorphanol given intravenously at dosages of 0.1, 0.3 and 0.5 mg/kg every 4 hours for 48 hours followed by once daily injections for a total of 21 days. The only detectable drug effects were slight transient ataxia observed occasionally in the high dosage group. No clinical, laboratory, or gross or histopathologic evidence of any butorphanol-related toxicity was encountered in the horses.

**INDICATIONS**

TORBUGESIC (butorphanol tartrate) is indicated for the relief of pain associated with colic in adult horses and yearlings. Clinical studies in the horse have shown that TORBUGESIC alleviates abdominal pain associated with torsion, impaction, intussusception, spasmotic and tympanic colic and postpartum pain.

**WARNINGS**

DO NOT USE IN HORSES INTENDED FOR HUMAN CONSUMPTION. NOT FOR HUMAN USE.

**CAUTION**

TORBUGESIC, a potent analgesic, should be used with caution with other sedative or analgesic drugs as these are likely to produce additive effects.

There are no well-controlled studies using butorphanol in breeding horses, weanlings and foals. Therefore, the drug should not be used in these groups.

**ADVERSE REACTIONS**

In clinical trials in horses, the most commonly observed side effect was slight ataxia which lasted 3 to 10 minutes. Marked ataxia was reported in 1.5% of the 327 horses treated. Mild sedation was reported in 9% of the horses.

**DOSEAGE**

The recommended dosage in the horse is 0.1 mg of butorphanol per kilogram of body weight (0.05 mg/lb) by intravenous injection. This is equivalent to 5 mL of TORBUGESIC for each 1000 lbs body weight.

The dose may be repeated within 3 to 4 hours but treatment should not exceed 48 hours.

Pre-clinical model studies and clinical field trials in horses demonstrate that the analgesic effects of TORBUGESIC are seen within 15 minutes following injection and persist for about 4 hours.

**HOW SUPPLIED**

50 mL vials TORBUGESIC (butorphanol tartrate) Veterinary Injection, 10 mg base activity per mL.

10 mL vials TORBUGESIC (butorphanol tartrate) Veterinary Injection, 10 mg base activity per mL.

Store at controlled room temperature 20°–25°C (68°–77°F) with excursions between 15°–30°C (59°–86°F).

**REFERENCES**


Distributed by:

Fort Dodge Animal Health
da division of Wyeth

a wholly owned subsidiary of Pfizer Inc

New York, NY 10017

Made in Spain

Revised: January 2012
Trimethoprim/sulfadiazine is rapidly absorbed and widely distributed after oral administration.

Susceptibility Testing:

- **Escherichia coli**: Sensitive
- **Staphylococcus aureus**: Sensitive
- **Pasteurella species**: Sensitive
- **Shigella species**: Sensitive
- **Haemophilus influenzae**: Sensitive
- **Bordetella bronchiseptica**: Sensitive
- **Haemophilus ducreyi**: Moderately Sensitive
- **Streptococcus pneumoniae**: Not Sensitive
- **Staphylococcus epidermidis**: Not Sensitive
- **Streptococcus faecalis**: Sensitive
- **Streptococcus pyogenes**: Sensitive

### AVERAGE MINIMUM INHIBITORY CONCENTRATION (MIC-mcg/ml)

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>TMP</th>
<th>SDZ</th>
<th>TMP/SDZ</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Escherichia coli</em></td>
<td>0.31</td>
<td>26.5</td>
<td>0.07</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>0.6</td>
<td>17.6</td>
<td>0.03</td>
</tr>
<tr>
<td><em>Pasteurella species</em></td>
<td>0.06</td>
<td>20.1</td>
<td>0.03</td>
</tr>
<tr>
<td><em>Salmonella species</em></td>
<td>0.15</td>
<td>61.0</td>
<td>0.02</td>
</tr>
<tr>
<td><em>Proteus species</em></td>
<td>1.3</td>
<td>24.5</td>
<td>0.05</td>
</tr>
</tbody>
</table>

As a result of the sequential double blockade of the metabolism of susceptible organisms by trimethoprim and sulfadiazine, the minimum inhibitory concentration (MIC) of trimethoprim/sulfadiazine is markedly less than that of either of the components used separately. Many strains of bacteria that are not susceptible to one of the components are susceptible to the combination. A synergistic effect between trimethoprim and sulfadiazine in combination has been shown experimentally both in vitro and in vivo (in dogs).

Trimethoprim/sulfadiazine is bactericidal against susceptible strains and is often effective against sulfonamide-resistant organisms. In vitro sulfadiazine is usually only bacteriostatic. The precise in vitro MIC of the combination varies with the ratio of the drugs present; but action of trimethoprim/sulfadiazine occurs over a wide range of ratios with an increase in the concentration of one of its components compensating for a decrease in the other. It is usual, however, to determine MICS using a constant ratio of 1 part trimethoprim in 20 parts of the combination.

The following table shows MICS using the above ratio, of bacteria which were susceptible to both trimethoprim (TMP) and sulfadiazine (SDZ). The organisms are those most commonly involved in conditions for which trimethoprim/sulfadiazine is indicated.

### AVERAGE MINIMUM INHIBITORY CONCENTRATION OF SULFADIAZINE-RESISTANT STRAINS (MIC-mcg/ml)

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>TMP Alone</th>
<th>SDZ Alone</th>
<th>TMP/SDZ</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Escherichia coli</em></td>
<td>0.32</td>
<td>&gt; 245</td>
<td>0.27</td>
</tr>
<tr>
<td><em>Proteus species</em></td>
<td>0.66</td>
<td>&gt; 245</td>
<td>0.32</td>
</tr>
</tbody>
</table>

Serum trimethoprim concentrations in horses following oral administration indicate rapid absorption of the drug; peak concentrations occur in 1.5 hours. The mean serum elimination halflife is 2 to 2.5 hours. Sulfadiazine absorption is slower, requiring 2.5 to 6 hours to reach peak concentrations. The minimum elimination halftime for sulfadiazine is 4 to 5.5 hours.

Usually, the concentration of an antibacterial in the blood and the in vivo MIC of the infecting organism indicate an appropriate period between doses of a drug. This does not hold entirely for trimethoprim/sulfadiazine because trimethoprim, in contrast to sulfadiazine, localizes in tissues and therefore, its concentration and ratio to sulfadiazine are higher than those in blood.

### Indications and Usage

Trimethoprim/sulfadiazine is indicated in horses where potent systemic antibacterial action against sensitive organisms is required. Trimethoprim/sulfadiazine is indicated where control of bacterial infections is required despite treatment of:

- Acute Strangles
- Acute Urogenital Infections
- Respiratory Tract Infections
- Wound Infections and Abscesses

### Contraindications

Trimethoprim/sulfadiazine should not be used in horses showing marked liver parenchymal damage, blood dyscrasias or in those with a history of sulfonamide sensitivity.

### Precautions

- Water should be readily available to horses receiving sulfonamide therapy.
- ADVERSE REACTIONS:
  - During clinical trials, one case of anorexia and one case of loose feces following treatment with the drug were reported.
  - Individual animal hypersensitivity may result in local or generalized reactions, sometimes fatal.
  - Anaphylactoid reactions, although rare, may also occur. Antidote: Epinephrine.

### Post Approval Experience

Horses have developed diarrhea during trimethoprim/sulfadiazine treatment, which could be fatal. If fecal consistency changes during trimethoprim/sulfadiazine therapy, discontinue treatment immediately and contact your veterinarian.

### Animal Safety

- Toxicity is low. The acute toxicity (LD50) of trimethoprim/sulfadiazine is greater than 5 g/kg orally in rats and mice. No significant changes were recorded in rats given doses of 600 mg/kg per day for 90 days.

### Pharmacology

- Following oral administration, trimethoprim/sulfadiazine is rapidly absorbed and widely distributed throughout body tissues. Concentrations of trimethoprim are usually higher in tissues than in blood.
- The levels of trimethoprim are high in lungs, kidneys and liver, and would be expected from its physical properties.

### Storage Conditions

Store at or below 30 C.

### How Supplied

TUCOPRIM Powder is available in the following package sizes:

- 400 gram bottle
- 2000 gram pails

ANADA #200-244, Approved by FDA

Made in China

Distributed by: Zoetics Inc.

Kalamazoo, MI 49007

Revised: January 2013

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