



PAIN & SEDATION

For their comfort. For your safety.

Always by your side as your dependable
partner in equine sedation and
pain management.



zoetis

The proven legacy to count on when safety matters most

Equine care is not for the faint of heart.

As beautiful and inspiring as your patients can be, their size and energy remind us to approach them with care and awareness. Even routine situations or procedures can pose significant risks. That's why we provide the highest-quality solutions to care for them safely.

We're always by your side with the #1 veterinarian-trusted products that help make up our comprehensive equine pain and sedation portfolio.¹

TRUSTED SOLUTIONS. UNWAVERING SUPPORT.

70+
years

Unmatched commitment

We've spent decades advancing horse care with breakthrough treatments and expert guidance. Since 1991, Dormosedan® Sterile Solution (*detomidine hydrochloride*) has been a game-changer and remains the #1 vet-trusted equine sedative.¹

360°
of support

Expert guidance

Our team is with you every step of the way to help ensure compassionate care and give your patients everything they need to feel their best, including sedation and pain management options backed by comprehensive support.

#1
vet preferred

Trusted care

Our trusted pain and sedation solutions continue to reinforce why equine veterinarians consider Zoetis their #1 go-to brand.²

The top two trusted solutions for the highest degree of confidence

Dormosedan and Torbugesic® (*butorphanol tartrate*) are cornerstones of the Zoetis Equine pain and sedation portfolio, trusted by practitioners like you.



DORMOSEDAN®
(detomidine hydrochloride)

- **Most frequently used** equine pain and sedation product by veterinarians¹
- **Ranked highest** for safety and efficacy by veterinarians across all equine pain and sedation products¹
- **Rated best** of all equine sedation products for predictability by veterinarians¹



Torbugesic® IV
BUTORPHANOL TARTRATE

- **Rated highest** for efficacy by veterinarians compared to competitor products¹
- Ranked by veterinarians as the **top of its class** compared to competitor products¹

As the most trusted equine pain and sedation solutions on the market, Dormosedan and Torbugesic have a proven track record of efficacy, safety and predictability, and they're backed by the Zoetis team.

Ranked #1 and #2
**most
trusted¹**



Ranked #1 and #2 in
**technical
support¹**

compared to competitor pain and
sedation products for horses

DORMOSEDAN®

(detomidine hydrochloride)

The #1 equine sedative and pain control solution¹

Sedation and analgesia you can count on every time, with a proven track record of safety and efficacy for over 30 years.

- Dormosedan delivers reliable sedation and analgesia in a single intravenous dose to help keep you safe and your patients comfortable
- Using Dormosedan alone significantly reduces or even eliminates the need for mixing products to achieve the desired results

SHELF LIFE AND STORAGE



Dormosedan has simple room temperature storage requirements

VS

Generic detomidine has a lower storage temperature and a limited shelf life of 28 days once the vial is punctured⁵



Scan to learn more about Dormosedan
Dormosedan.com



Dormosedan maintains the clear advantage, providing predictable, effective sedation and analgesia due to high selectivity for alpha-2 receptors.



Documented benefits	Dormosedan (detomidine hydrochloride)	Xylazine hydrochloride
Alpha-2 adrenoceptor agonist ^{4,5}	✓	✓
#1 vet-trusted equine sedative ¹	✓	✗
More potent sedative ^{4,5}	✓	✗
More potent analgesic ^{4,5}	✓	✗
Longer duration of action ^{4,5}	✓	✗
Greater specificity for alpha-2 receptors* ⁶	✓	✗
Convenient dosing schedule ¹	✓	✓
Reversible ⁷	✓	✓
Rapid onset of sedation ^{4,5}	✓	✓
Inherent safety: additional doses prolong but do not deepen sedation (plateau effect) ^{4,5}	✓	✓

*Sedatives with low alpha-2 specificity increase the potential for aberrant effects caused by activity at non-alpha-2 receptor sites. Xylazine can bind with alpha-1 and non-alpha-2 receptor sites, producing variable neurological effects in rats.⁴

Dormosedan allows dosing flexibility so you can accurately regulate the depth and length of sedation and analgesia.

Dormosedan dosing reference guide

Dose: 20 or 40 mcg/kg = 10 mg or 20 mg/500 kg (1,100 lbs) = 1 or 2 mL/500 kg (1,100 lbs) **Administration:** IV or IM

Horse body weight (kg)	Horse body weight (lbs)	IV/IM mg	IV/IM mL	Clinical effects	IV/IM sedation duration	IV analgesia duration**
100	220	2 or 4	0.2 or 0.4	Beginning effects: IV 2–4 minutes IM 3–5 minutes Optimal effects for IV and IM: 10–15 minutes	1 mL per 1,100 lbs: 30–90 minutes 2 mL per 1,100 lbs: 1.5–2 hours	1 mL per 1,100 lbs: 30–45 minutes 2 mL per 1,100 lbs: 45–75 minutes
200	440	4 or 8	0.4 or 0.8			
300	660	6 or 12	0.6 or 1.2			
400	880	8 or 16	0.8 or 1.6			
500	1,100	10 or 20	1.0 or 2.0			
600	1,320	12 or 24	1.2 or 2.4			
700	1,540	14 or 28	1.4 or 2.8			

**Analgesia has not been evaluated in IM administration.

Dormosedan can facilitate a wide variety of procedures.



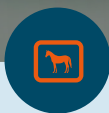
Husbandry

Body clipping
 Difficulty with trailer loading
 Challenging or painful farrier cases
 First turnout after extended layup
 Bandage changes



Diagnostic Procedures

Endoscopy
 Gastroscopy
 Sinoscopy
 Colic workup
 Bronchoalveolar lavage (BAL)
 Transtracheal wash (TTW)



Diagnostic Imaging

Radiography
 Ultrasound
 Nuclear scintigraphy
 Positron emission tomography (PET) scan
 Magnetic resonance imaging (MRI)
 Computed tomography (CT)



Routine Procedures

Joint injections
 Wound management
 Cast and splint application
 Caslick's procedure
 Flushing nasolacrimal ducts



Surgical Procedures

Constant rate infusions (CRI) or injection for standing surgery
 Standing laparoscopy
 Pressor support while under general anesthesia
 Epidural
 Prolongation of recovery if needed



Dental Care

Complete oral examination with mouth speculum
 Power floating
 Wolf tooth extraction
 Dental extraction

Many procedures also require judicious use of local anesthetics such as Carbocaine®-V (2% mepivacaine hydrochloride, USP) sterile aqueous solution.



Torbugesic® IV
BUTORPHANOL TARTRATE

Proven pain relief. Trusted support.

Torbugesic® (butorphanol tartrate) provides a safe and effective way of relieving your patients' discomfort, and it's the #1 veterinarian-trusted butorphanol product.¹

- Veterinarians rank Torbugesic as the most effective butorphanol product available¹
- Torbugesic is an integral part of the Zoetis industry-leading pain and sedation portfolio, which is supported by a team of equine experts who always have your back



Scan to learn more
about Torbugesic
[Torbugesic.com](https://www.Torbugesic.com)

Ensure compassionate care with an effective pain solution.

Use Torbugesic to alleviate abdominal pain associated with:

Postpartum
pain

Torsion

Impaction

Intussusception

Spasmodic
colic

Tympanic
colic

Torbugesic dosing information

Concentration

10 mg/mL butorphanol tartrate

Administration

IV

Dose

0.05 mg butorphanol per lb
(1/2 mL per 100 lbs)

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

Explore the extended portfolio of pain and sedation solutions for reliable relief

Zoetis' safe and reliable portfolio of pain and sedation solutions provides comfort for your patients during minor surgical and diagnostic procedures, effectively addressing equine pain and inflammation.

Carbocaine®-V Sterile Aqueous Solution (mepivacaine hydrochloride)

- Reliable local anesthetics like Carbocaine-V are essential in equine practice, facilitating everything from lameness exams to major surgery
- Carbocaine-V provides rapid effective local anesthesia lasting for several hours
 - Longer duration of action than lidocaine⁸
 - More rapid onset of action than bupivacaine⁸
 - Less cytotoxic than lidocaine or bupivacaine⁸

Carbocaine-V offers the flexibility to be used in a wide variety of routine procedures.⁹

Procedure	Use instances	Dose
Nerve block	• Diagnosis of lameness • Regional analgesia • Local block for wound repair or surgery	3–15 mL
Intra-articular anesthesia	• Diagnosis of lameness • Osteoarthritis	10–15 mL
Standing epidural anesthesia	• Standing surgical procedures • Pain management	5–20 mL
Infiltration	• Wound debridement and repair • Standing surgical procedures • Facilitating difficult joint and nerve blocks (performed alone or in combination with nerve block or intra-articular anesthesia)	To effect as required
Anesthesia of laryngeal mucosa	• Topically, by infiltration or by a combination of the two • Prior to ventriculectomy	Topically: 3 mL per application by spray with a total of 25–40 mL Infiltration: 20–50 mL



Scan to learn more
about Carbocaine-V
CarbocaineV.com



Scan to learn more
about Depo-Medrol
DepoMedrolPI.com

Depo-Medrol® Sterile Aqueous Suspension (methylprednisolone acetate)

- An anti-inflammatory corticosteroid used for the treatment of arthritis as well as certain allergies and skin conditions in horses. Can be administered both intrasynovially and intramuscularly.
- Always administer the lowest therapeutic dose based on the individual case
- When used to treat arthritis, Depo-Medrol provides relief from pain within 12 to 24 hours of intrasynovial injection, and that relief lasts for an average of 3 to 4 weeks
- Comes in two concentrations (20 mg/mL or 40 mg/mL)



Scan to learn more
about Ketofen
KetofenPI.com

Ketofen® Injectable Solution (ketoprofen)

- Recommended for the alleviation of pain and inflammation associated with musculoskeletal disorders, including synovitis.¹⁰ Administer 1 mg per pound of body weight (1 mL/100 lbs) IV once daily for up to 5 days.
- Can also provide valuable supportive therapy for the management of pain associated with equine colic¹¹
- Provides a similar level of analgesia as flunixin meglumine for management of mild visceral post-operative pain in horses¹²
- Ketofen has the shortest recommended pre-race withdrawal time of any NSAID on the Horseracing Integrity and Safety Authority's list of controlled therapeutic substances¹³

Visit United States Equine Federation (USEF) and
Racing Medication & Testing Consortium (RMTC)
for the latest guidelines



USEF



RMTC

DORMOSEDAN® GEL

[detomidine hydrochloride]

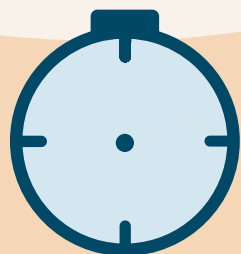
Care for them with confidence

Oral formulation of the #1 veterinarian-trusted equine sedative¹
and the only FDA-approved oral sedative of its kind that reliably
keeps horses calm and helps keep handlers safe.

Convenient and consistent oral sedation.

For routine horse care and husbandry procedures where horses may become anxious and difficult to work with, Dormosedan® Gel (detomidine hydrochloride) can provide a safe solution.

- Mild-standing sedative available with a veterinarian's prescription
- Easy-to-use, single-dose syringe administered **under the horse's tongue**
- Helps facilitate a calm experience for both horses and handlers when a veterinarian cannot be present



Onset of sedation
40 minutes

Recovery in
3-4 hours

90-180 mins
of sedation



Scan to learn more
about Dormosedan Gel
DormGel.com

Recommend as a safe alternative to physical restraints
for use before a wide variety of procedures:

Farrier
work

Bandaging

Basic
first-aid
care

Body
clipping

Mane
pulling

Sheath
cleaning

First-time
supervised
turnout on
a dry lot for
fractious
horses

Fireworks

ADMINISTRATION AND DOSING INFORMATION

STEP ONE

Use impermeable gloves when handling the product.

Remove the horse's access to all food and water sources.

Remove the syringe from the outer carton.

While holding the plunger, turn the ring-stop on the plunger until the ring slides freely up and down the plunger.



STEP TWO

Position the ring so that the side nearest the barrel is at the desired volume marking (see dosing information).

Turn the ring to secure it in place. Test the ring to ensure it does not slide.

Make sure the horse's mouth contains no feed.



STEP THREE

Remove the cap and place the syringe tip into the corner of the horse's mouth **underneath the tongue**.

Depress the plunger until the ring-stop contacts the barrel, depositing the product beneath the tongue.



STEP FOUR

Take the syringe out of the horse's mouth, recap and return it to the outer carton for disposal.

Remove and discard gloves.

Place the horse in a safe, quiet area for a minimum of 40 minutes while the sedation takes effect.

Withhold food and water until the sedative effects wear off.



Approximate body weight (lbs)	Dose volume (mL)
330–439	1.00
440–549	1.25
550–659	1.50
660–769	1.75
770–879	2.00
880–989	2.25
990–1,099	2.50
1,100–1,209	2.75
1,210–1,320	3.00

Ranked #1 in
**ease of
administration**
among pain and sedation
products by veterinarians¹



Confidence in moments that matter most

From the most trusted sedatives and pain management solutions to regenerative medicine devices and beyond, our product portfolios work together to provide comprehensive care while keeping your patients' safety top of mind.



Regenerative approaches to musculoskeletal injury

Advanced regenerative medicine devices like **Pro-Stride® APS**, **Restigen® PRP** and **Centrate® BMA** allow you to focus your efforts on healing with horsepower. Sedation and local anesthetics are often required to ensure that injections can be performed safely and without accidental loss of high-value therapeutic products.



Regenerative medicine devices

Visit our website for a comprehensive overview of the Zoetis regenerative medicine family of devices and resources for your practice.



Innovations in equine dentistry

Recent rapid progress in this field has been facilitated by reliable standing sedation protocols.¹⁴ The availability of sedatives like **Dormosedan** paired with the use of effective local anesthetics like **Carbocaine-V** have minimized the need for general anesthesia for even complex dental procedures.¹⁴



Dental awareness toolkit

Download this package of assets to help promote dental health awareness and dental services at your practice.



Advanced imaging techniques— transforming equine care

Standing image acquisition is now a reality for many modalities, including CTs and MRIs.¹⁵ You need solid sedation protocols to allow for safe image acquisition and to minimize movement artifacts. **Dormosedan** provides the most trusted and reliable solution.



Standing surgery— safer for you and the patient

Using effective sedatives and local anesthetics like **Dormosedan** and **Carbocaine-V**, many procedures that were once exclusively performed under general anesthesia can now be performed safely in the standing horse.¹⁶ This approach avoids the risk of recovery from general anesthesia and can also reduce procedure costs for your clients.



Ensuring compassionate reproductive care

Zoetis' safe and reliable portfolio of pain and sedation solutions helps provide comfort for both you and your patients. When dealing with a complicated or difficult foaling, **Torbugesic** can provide valuable pain control for the mare's postpartum discomfort.



Mare & Foal Care solutions

Access valuable resources for the reproductive care of mares and foals.

We're with you every step of the way

23

Equine specialists

8

Dedicated equine technical service veterinarians

30+

Industry partnerships and sponsorships

1:1

Expert product support

45+

Customer service and inside sales support

1.2K+

R&D colleagues bringing innovation to market

We provide 360 degrees of support for horses and their caregivers. To help you continually build your knowledge, our technical services and product support teams offer ongoing guidance on equine care best practices, disease states and product solutions.

Contact us for one-on-one product support
Monday-Friday, 9 a.m.-6:30 p.m. ET

📞 1-888-963-8471 ✉️ supportUS@zoetis.com

Our Veterinary Medical Information and Product Support (VMIPS) team includes veterinarians and technicians with more than 50 years of combined experience, always by your side to answer questions regarding the safety and appropriate use of Zoetis products.



Our commitment to veterinarians and the industry

CONTINUING EDUCATION

We support veterinary organizations and ongoing funding for continuing education and veterinary student scholarships.



INVESTING IN THE INDUSTRY

We are committed to a sustainable equine industry and support groups that contribute to the broader community.



RESEARCH

We are devoted to advancing equine research to help make horses' lives better, one discovery at a time.



VETERINARIAN AND EQUINE WELL-BEING

We support programs for veterinarian well-being, disaster relief for the equine community and much more.



Carbocaine®-V

(mepivacaine hydrochloride injection)

Sterile Aqueous Solution



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'-piperidoxylidide 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

Do not use in horses intended for human consumption. Not for human use. Keep out of reach of children.

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.

Approved by FDA under NADA # 100-703

zoetis

Distributed by:

Zoetis Inc.

Kalamazoo, MI 49007

Revised: August 2019

4020551 - PH 1085A&P

Depo-Medrol® (methylprednisolone acetate injectable 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 is available in two concentrations, 20 mg per mL and 40 mg per mL. Each mL of these preparations contains:

	20 mg	40 mg
Methylprednisolone acetate	20 mg	40 mg
Polyethylene glycol 3350	29.6 mg	29.1 mg
Sodium chloride	8.9 mg	8.7 mg
Mystiv® gamma-picolinium chloride added as preservative	0.197 mg	0.194 mg

When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.

The chemical name for methylprednisolone acetate is pregna-1,4-diene-3,20-dione, 21-(acetoxyl)-11,17-dihydroxy-6-methyl-, (6 α ,11 β)-.

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 corticosteroids of affording 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 1.13 to 2.1, with an average of 1.5. In anti-inflammatory activity, as 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. The duration of plasma steroid levels following rapid intravenous injection in intact dogs is appreciably longer for methylprednisolone than for prednisolone, the respective "half-life" value for the two steroids being 80.9 $\pm$ 7.5 minutes for methylprednisolone and 71.3 $\pm$ 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 has been found useful in alleviating the pain and lameness associated with acute localized arthritic conditions and generalized arthritic conditions. It has been used successfully to treat rheumatoid arthritis, traumatic arthritis, osteoarthritis, periarthritis, tenositis, synovitis, tenosynovitis, bursitis, and myositis of muscles; traumatic arthritis, osteoarthritis, and generalized arthritic conditions of dogs. Remission of musculoskeletal conditions may be permanent, or symptoms may recur, depending on the cause and extent of structural degeneration.

Allergic Conditions. This preparation is especially beneficial in relieving pruritus and inflammation of allergic dermatitis, acute moist dermatitis, dry eczema, urticaria, bronchial 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 a few days 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 SOLU-DELTA-CORTEF® Sterile Powder containing prednisolone sodium succinate, as well as other appropriate treatments, should be used.

Overwhelming Infections with Severe Toxicity. In dogs and cats moribund from overwhelmingly severe infections for which antibacterial therapy is available (eg, critical pneumonia, pyometritis), DEPO-MEDROL may be lifesaving, acting to inhibit the inflammatory reaction, which itself may be lethal; preventing vascular collapse and preserving the integrity of the blood vessels; modifying the patient's reaction to drugs; and preventing or reducing the exudative reaction which often complicates certain infections. As supportive therapy, it 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. Corticosteroid therapy in the presence of infection should be administered for the shortest possible time compatible with maintenance of an adequate response, and antibacterial 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.

Other Conditions. In certain conditions where it is desired to reduce inflammation, vascularization, fibroblastic infiltration, and scar tissue, the use of DEPO-MEDROL should be considered. Snakebite of dogs also is an indication for the use of this suspension because of its anti-toxicemic, anti-shock, and anti-inflammatory activity. It is particularly effective in reducing swelling and preventing sloughing, its employment in the treatment of such conditions is recommended as a supportive measure to standard procedures and time-honored treatments and will give comfort to the animal and hasten complete recovery.

CONTRAINDICATIONS

Systemic therapy with methylprednisolone acetate, as with other corticoids, is contraindicated in animals with arrested tuberculosis, peptic ulcer, and Cushing's syndrome. The presence of active tuberculosis, diabetes mellitus, osteoporosis, renal insufficiency, predisposition to thrombophlebitis, hypertension, or congestive heart failure necessitates carefully controlled use of corticosteroids. Intrasynovial, intrathecal, or other injections of corticosteroids for local effect are contraindicated in the presence of acute infectious conditions. Exacerbation of pain, further loss of joint motion, with fever and malaise following injection may indicate that the condition has become septic. Appropriate antibacterial therapy should be instituted immediately.

WARNING

Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of 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.

Not for human use. Do not use in horses intended for human consumption.

PRECAUTIONS

DEPO-MEDROL 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 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. 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 toxicity, methylprednisolone acetate therapy in conjunction with appropriate antibacterial therapy is effective in reducing mortality and morbidity. Without conjoint 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 or potassium depletion has been observed at the doses recommended, animals receiving methylprednisolone acetate, as with all corticoids, should be under close observation for possible untoward effects. If symptoms of hypopotassemia (hypokalemia) should occur, corticoid therapy should be discontinued and potassium chloride administered by continuous intravenous drip.

Since this drug lacks significant mineralocorticoid activity in usual therapeutic doses, it is not likely to afford adequate support in states of acute adrenocortical insufficiency. For treatment of the latter, the parent adrenocortical steroids, hydrocortisone or cortisone, should be used.

DOSEAGE AND ADMINISTRATION

INTRAMUSCULAR

Following intramuscular injection of methylprednisolone acetate, a prolonged systemic effect results. The dose varies with the size of the animal patient, the severity of the condition under treatment, 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 under treatment, the dose may range from 2 mg in miniature breeds to 40 mg in medium breeds, 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 smallest effective (ie, individualized) dose is established. MEDROL® Tablets containing methylprednisolone 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 highly soluble SOLU-DELTA-CORTEF® Sterile Powder containing prednisolone 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 relief varies, but averages three to four weeks, with a range of one to five or more 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 adjunct to general therapeutic measures to effect suppression of inflammation in one or a few peripheral structures when (1) the disease is limited to one or a few peripheral structures; (2) the disease is widespread with one or a few peripheral structures actively inflamed; (3) 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 corticotropin is contraindicated; (5) joints show early but actively progressing deformity to enhance the effect of physiotherapy and corrective procedures; and (6) surgical or other orthopedic corrective measures are to be or have been done.

The action of DEPO-MEDROL injected intrasynovially appears to be well localized since significant metabolic effects characteristic of systemic administration of adrenal steroids have not been observed. In a few instances mild and transient improvement of 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 employed.

Procedure for Intrasynovial Injection. The anatomy of the area to be injected should be reviewed in order to assure that the suspension is properly placed and to determine that large blood vessels or nerves are avoided. The injection site is located where the synovial cavity is most superficial. The area is prepared for aseptic injection of the medicine by the removal of hair and cleansing of the skin with alcohol or Mercresin® tincture. A sterile 18- to 21-gauge needle for horses, 20- to 22-gauge needle for dogs, on a dry syringe is quickly inserted into the synovial space and a small amount of synovial fluid withdrawn. If there is an excess of synovia and more than 1 mL of suspension is to be injected, it is well to aspirate a volume of fluid comparable to that which is to be injected. With the needle in place, the aspirating syringe is removed and replaced by a second syringe containing the proper amount of suspension which is then injected. In some animals a transient pain is elicited immediately upon injection into the affected cavity. This pain varies from mild to severe and may last for a few minutes up to 12 hours. After injection, the structure may be moved gently a few times to aid mixing of the synovial fluid and the suspension. The site may be covered with a small sterile dressing.

Areas not suitable for injection are those that are anatomically inaccessible such as spinal joints and those like the sacroiliac joints, which are devoid of synovial space. Treatment failures are most frequently the result of failure to enter the synovial space. If failures occur when injections into the synovial spaces are certain, as determined by aspiration of fluid, repeated injections are usually futile. Local therapy does not alter the underlying disease process, and whenever possible comprehensive therapy including physiotherapy and orthopedic correction should be employed.

The single intrasynovial dose depends on the size of the part, which corresponds to the size of the animal. The interval between repeated injections depends on the duration of relief obtained.

Horses. The average initial dose for a large synovial space in horses is 120 mg with a range from 40 to 240 mg. Smaller spaces will require a correspondingly lesser dose.

Dogs. The average initial dose for a large synovial space in dogs is 20 mg. Smaller spaces will require a correspondingly lesser dose.

Store 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, 20 mg/mL is available in 20 mL vials, and 40 mg/mL is available in 5 mL vials.

Approved by FDA under NADA # 012-204

zoetis

Distributed by:

Zoetis Inc.

Kalamazoo, MI 49007

Revised: May 2019

50334301A&P

DORMOSEDAN®



(detomidine hydrochloride)

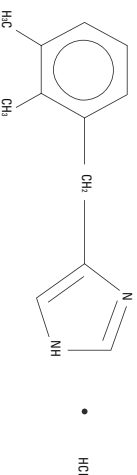
Sedative and Analgesic For Use in Horses Only

*Sterile 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. The chemical name is 1H imidazole, 4-[[2,3-dimethyl(phenyl) methyl]- hydrochloride and the generic name is detomidine hydrochloride. It is a white, crystalline, water-soluble substance having a molecular weight of 222.7. The molecular formula is $C_{12}H_{14}N_2 \cdot HCl$.

CHEMICAL STRUCTURE:



Each mL of Dormosedan® contains 10.0 mg detomidine hydrochloride, 1.0 mg methylparaben, 5.9 mg sodium chloride, and water for injection, q.s.

CLINICAL PHARMACOLOGY: Dormosedan®, a non-narcotic sedative and analgesic, is a potent α_2 -adrenoreceptor agonist which produces sedation and superficial and visceral analgesia which is dose dependent in its depth and duration. Profound lethargy and a characteristic lowering of the head with reduced sensitivity to environmental stimuli (sounds, etc.) are seen with detomidine. A short period of incoordination is characteristically followed by immobility and a firm stance with front legs well 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 detomidine administration, heart rate is markedly decreased, blood pressure is initially elevated, and then a steady decline to normal is seen. A transient change in the conductivity of the cardiac muscle may occur, as evidenced by partial atrioventricular (AV) and sinoauricular (SA) blocks. This change in the conductivity of the cardiac muscle may be prevented by IV administration of atropine at 0.02 mg/kg of body weight. No effect on blood clotting time or other hematological parameters was encountered at dosages of 20 or 40 mcg/kg of body weight. Respiratory responses include an initial slowing of respiration within a few seconds to 1–2 minutes after administration, increasing to normal within 5 minutes. An initial decrease in tidal volume is followed by an increase.

INDICATIONS: Dormosedan® is indicated for use as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings. It has been used successfully for the following: to calm fractious horses, to provide relief from abdominal pain, to facilitate bronchoscopy, bronchoalveolar lavage, nasogastric intubation, nonreproductive rectal palpations, suturing of skin lacerations, and castrations. Additionally, an approved, local infiltration anesthetic is indicated for castration.

CONTRAINDICATIONS: Dormosedan® should not be used in horses with pre-existing AV or SA block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Intravenous potentiated sulfonamides should 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 uncontrolled 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 human use. Keep out of reach of children.

HUMAN SAFETY INFORMATION: Care should be taken to assure that detomidine hydrochloride is not inadvertently ingested as safety studies have indicated that the drug is well absorbed when administered orally. Standard ocular irritation tests in rabbits using the proposed market formulation have shown detomidine hydrochloride to be nonirritating to eyes. Primary dermal irritation tests in guinea pigs using up to 5 times the proposed market concentration of detomidine hydrochloride on intact and abraded skin have demonstrated that the drug is nonirritating to skin and is apparently poorly absorbed dermally. However, in accordance with prudent clinical procedures, exposure of eyes or skin should be avoided and affected areas should be washed immediately if exposure does occur. As with all injectable drugs causing profound physiological effects, routine precautions should be employed by practitioners when handling and using loaded syringes to prevent accidental self-injection.

PRECAUTIONS: Before administration, careful consideration should be given to administering Dormosedan® to horses approaching or in endotoxic or traumatic shock, to horses with advanced liver or kidney disease, or to horses under stress from extreme heat, cold, fatigue, or high altitude. Protect treated horses from temperature extremes. Some horses, although apparently deeply sedated, may still respond to external stimuli. Routine safety measures should be employed to protect practitioners and handlers. Allowing the horse to stand quietly for 5 minutes before administration and for 10–15 minutes after injection may improve the response to Dormosedan®.

Dormosedan® is a potent α_2 -agonist, and extreme caution should be exercised in its use with other sedative or analgesic drugs for they may produce additive effects.

When using any analgesic to help alleviate abdominal pain, a complete physical examination and diagnostic work-up are necessary to determine the etiology of the pain. Food and water should be withheld until the sedative effect of Dormosedan® has worn off.

ADVERSE REACTIONS: Occasional reports of anaphylactic-like reactions have been received, including 1 or more of the following: urticaria, skin plaques, dyspnea, edema of the upper airways, trembling, recumbency, and death. **The use of epinephrine should be avoided since epinephrine may potentiate the effects of α_2 -agonists.** Reports of mild adverse reactions have resolved uneventfully without treatment. Severe adverse reactions should be treated symptomatically. As with all α_2 -agonists, the potential for isolated cases of hypersensitivity exist, including paradoxical response (excitation).

CONTACT INFORMATION: For a copy of the Safety Data Sheet or to report adverse reactions, call Zoetis Inc. at 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VEIS or www.fda.gov/repportanimalae.

SIDE EFFECTS: Horses treated with Dormosedan® exhibit hypertension. Bradycardia routinely occurs 1 minute after injection. The relationship between hypertension and bradycardia is consistent with an adaptive baroreceptor response to the increased pressure and inconsistent with a primary drug-induced bradycardia. Piloerection, sweating, salivation, and slight muscle tremors are frequently seen after administration. Partial transient penis prolapse may be seen. Partial AV and SA blocks may occur with decreased heart and respiratory rates. Urination typically occurs during recovery at about 45–60 minutes posttreatment, depending on dosage. Incoordination or staggering is usually seen only during the first 3–5 minutes after injection, until animals have secured a firm footing.

Because of continued lowering of the head during sedation, mucus discharges from the nose and, occasionally, edema of the head and face may be seen. Holding the head in a slightly elevated position generally prevents these effects.

OVERDOSAGE: Detomidine hydrochloride is tolerated in horses at up to 200 mcg/kg of body weight (10 times the low dosage and 5 times the high dosage). In safety studies in horses, detomidine hydrochloride at 400 mcg/kg of body weight administered daily for 3 consecutive days produced microscopic foci of myocardial necrosis in 1 of 8 horses.

DOSEAGE AND ADMINISTRATION:

For Sedation: Administer Dormosedan® IV or IM at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of Dormosedan® per 100 kg or 220 lb), depending on the depth and duration of sedation required. Onset of sedative effects should be reached within 2–4 minutes after IV administration and 3–5 minutes after IM administration. Twenty mcg/kg will provide 30–90 minutes of sedation and 40 mcg/kg will provide approximately 90 minutes to 2 hours of sedation.

For Analgesia: Administer Dormosedan® IV at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of Dormosedan® per 100 kg or 220 lb), depending on the depth and duration of analgesia required. Twenty mcg/kg will usually begin to take effect in 2–4 minutes and provide 30–45 minutes of analgesia. The 40 mcg/kg dose will also begin to take effect in 2–4 minutes and provide 45–75 minutes of analgesia.

For Both Sedation and Analgesia: Administer Dormosedan® IV at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of Dormosedan® per 100 kg or 220 lb), depending on the depth and duration of sedation and analgesia required.

Before and after injection, the animal should be allowed to rest quietly.

STORAGE: Store at controlled room temperature 15°–30°C (59°–86°F) in the absence of light.

HOW SUPPLIED: Dormosedan® is supplied in 5- and 20-mL multidose vials.

Approved by FDA under NADA # 140-862

Manufactured by:



Karion Corporation
Espoo, Finland

zoetis

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Revised: September 2022
107224-11A&P

(detomidine hydrochloride)
Alpha₂-agonist oromucosal gel

For Sedation and Restraint in Horses Only

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

DORMOSEDAN (detomidine hydrochloride) GEL is a synthetic alpha₂-adrenoceptor agonist with sedative properties. Each mL of DORMOSEDAN GEL contains 7.6 mg detomidine hydrochloride. The chemical name is 1H indazole, 4-[(2,3-dimethylphenyl)methyl]-hydrochloride. Detomidine hydrochloride is a white, crystalline, water-soluble substance having a molecular weight of 222.7. The molecular formula is C₁₂H₁₄N₂HCl and the structural formula is

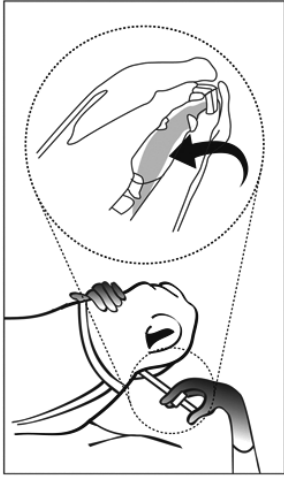


DOSAGE AND ADMINISTRATION:

DORMosedan GEL produces sedation when administered sublingually at 0.018 mg/lb (0.040 mg/kg). DORMosedan GEL must be placed beneath the tongue of the horse and is not meant to be swallowed. The dosing syringe delivers the product in 0.25 mL increments. The following dosing table may be used to determine the correct dose of DORMosedan GEL (Table 1).

Approximate body weight (lb)	Range of doses (mg/lb)	Approximate body weight (kg)	Range of doses (mg/kg)	Dose volume (mL)
330-439	0.022-0.017	150-199	0.051-0.038	1.00
440-549	0.022-0.017	200-249	0.047-0.038	1.25
550-659	0.021-0.017	250-299	0.046-0.038	1.50
660-769	0.020-0.017	300-349	0.044-0.038	1.75
770-879	0.019-0.017	350-399	0.043-0.038	2.00
880-989	0.019-0.017	400-449	0.043-0.038	2.25
990-1099	0.019-0.017	450-499	0.042-0.038	2.50
1100-1209	0.019-0.017	500-549	0.042-0.038	2.75
1210-1320	0.019-0.017	550-600	0.041-0.038	3.00

The following picture demonstrates correct administration of DORMOSEDAN GEL beneath the tongue.



For the best results, allow adequate time (a minimum of 40 minutes) between administration of DORMOSEDAN GEL and beginning the procedure. In general, horses show sedative effects lasting approximately 90-180 minutes.

Withhold food and water until the sedative effects of the product wear off.

Clinical field study: In a US field study of 270 horses sedated to facilitate completion of various veterinary and husbandry procedures, the following adverse reactions were reported in 202 horses treated with DORMOSEDAN GEL and 68 horses treated with placebo:

Clinical Sign	DORMOSEDAN GEL N = 202	Placebo N = 68
Sweating	20	0
Penile relaxation	12	0
Bradycardia (≤ 20 bpm)	11	0
Second degree AV block	9	0
Frequent urination	9	0
Piloerection	4	0
Marked ataxia	3	0
Facial/oral edema	3	0
Hypersalivation	2	0
Nasal discharge	2	0
Flatulence	1	0
Muscle tremors	1	1
Epiphora	1	0
Pale mucous membranes	1	0
Swollen sheath	1	0

Mild ataxia (horse stable but swaying slightly) was observed in 54% of DORMESEDAN GEL-treated horses and in 4% of the placebo-treated horses at 40 minutes post treatment administration. Moderate ataxia was observed in 25% of DORMESEDAN GEL-treated horses (0% placebo) at 40 minutes post treatment. Moderate to marked ataxia continued to 90 minutes for 5% and to 120 minutes for 4% of DORMESEDAN GEL-treated horses.

A prospective, randomized, masked, multi-center study was conducted to evaluate under field conditions, whether DORMOSEDAN GEL provided sufficient sedation and restraint in horses to successfully conduct procedures requiring administration of a sedative. Two hundred and seventy client-owned horses of any breed or sex were sedated to facilitate grooming (including cleaning of the prepuce), hoof care, floating teeth (manually), passage of a nasogastric tube or endoscope, 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 either 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 98 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

Ability to perform the procedure score*	DORMOSEDAN GEL N=129	Placebo N=42
0	16	38
1	15	15
2	44	2
3	54	1
Success (score 2 or 3)	98	3

* 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 prepuce (81%), manual floating of teeth (89%), hoof trimming or shoeing (88%), passage of a nasogastric tube or endoscope (80%), 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/ocular discharge, and congestion of oral mucous membranes. Ataxia, sweating, and reversible perile 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.

Approved by FDA under NADA # 141-306



Mfd by:
ORION PHARMA
Orion Corporation
Turku, Finland

Distributed by:
zoetis
Zoetis Inc.
Kalamazoo, MI 49007

Revised: March 2022

CLIENT INFORMATION SHEET FOR OWNER/HANDLER USE AND SAFETY:

This summary contains important information about Dormosedan (detomidine hydrochloride) 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 an anxious 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.

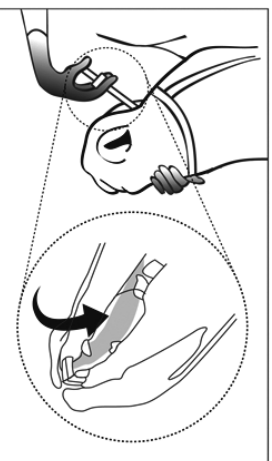
Contact Information

For a copy of the Safety Data Sheet or to report adverse reactions, call 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 www.fda.gov/reportanimalae.

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.

Revised: March 2022



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.

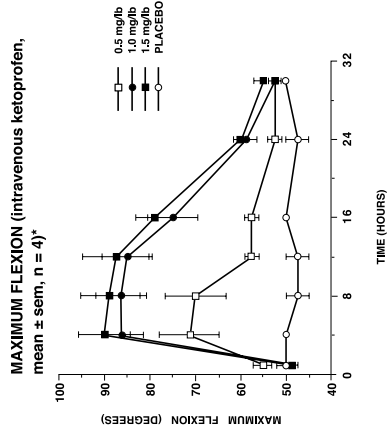
DESCRIPTION

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

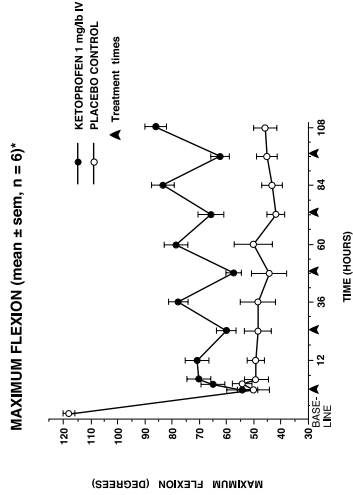
KETOFEN is a non-narcotic, non-steroidal anti-inflammatory agent with analgesic and antipyretic properties.

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 carpalis model as depicted in the following graph.



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

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.



*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 below 25°C (77°F), with brief excursions permitted between 0°C - 40°C (32°F - 104°F). Use contents within 4 months of first vial puncture.

Approved by FDA under NADA # 140-269

zoetis

Manufactured by:

Zoetis Manufacturing and Research Spain, S.L.
Girona, Spain

Distributed by:

Zoetis Inc.
Kalamazoo, MI 49007

July 2019

Torbugesic® (butorphanol tartrate injection)

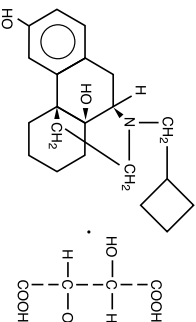
CAUTION

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

DESCRIPTION

TORBUGESIC (butorphanol tartrate injection) is a totally synthetic, centrally acting, narcotic agonist-antagonist analgesic with potent antitussive activity. It is a member of the phenanthrene series. The chemical name is Morphinan-3, 14-diol, 17-(cyclobutylmethyl)-, (+), (-)- (R*, R†)-2,3-dihydroxybutanedicarboxate (1:1) (salt). It is a white, crystalline, water soluble substance having a molecular weight of 477.55; its molecular formula is C₂₁H₂₉NO₂·C₄H₆O₆.

Chemical Structure



Each mL of TORBUGESIC contains 10 mg butorphanol base (as butorphanol tartrate), 3.3 mg citric acid, 6.4 mg sodium citrate, 4.7 mg sodium chloride, and 0.1 mg benzethonium chloride, q.s. with water for injection.

Clinical Pharmacology

Comparative Pharmacology
In animals, butorphanol has been demonstrated to be 4 to 30 times more potent than morphine and pentazocine (Talwin®) respectively.¹ In humans, butorphanol has been shown to have 5 to 7 times the analgesic activity of morphine and 20 times that of pentazocine.^{2,3}

Butorphanol has 15 to 20 times the oral antitussive activity of codeine or dextromethorphan in dogs and guinea pigs.⁴

As an antagonist, butorphanol is approximately equivalent to nalorphine and 30 times more potent than pentazocine.¹

Cardiopulmonary depressant effects are minimal after treatment with butorphanol as demonstrated in dogs⁵, humans^{6,7} and horses.⁸

Unlike classical narcotic agonist analgesics which are associated with decreases in blood pressure, reduction in heart rate and concomitant release of histamine, butorphanol does not cause histamine release.¹

Furthermore, the cardiopulmonary effects of butorphanol are not distinctly dosage-related but rather reach a ceiling effect beyond which further dosage increases result in relatively lesser effects.

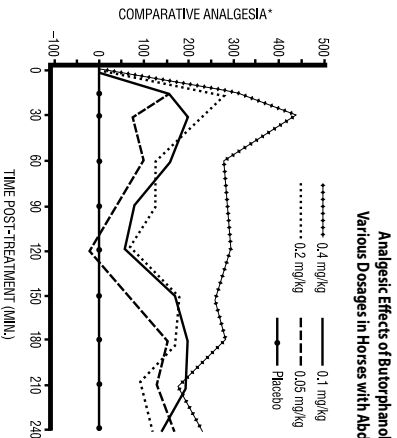
Reproduction: Studies performed in mice and rabbits revealed no evidence of impaired fertility or harm to the fetus due to butorphanol tartrate. In the female rat, parental administration was associated with increased nervousness and decreased care for the newborn, resulting in a decreased survival rate of the newborn. This nervousness was seen only in the rat species.

Pharmacology

Following intravenous injection in horses, butorphanol is largely eliminated from the blood within 3 to 4 hours. The drug is extensively metabolized in the liver and excreted in the urine.

In ponies, butorphanol given intramuscularly at a dosage of 0.22 mg/kg, was shown to alleviate experimentally induced visceral pain for about 4 hours.⁹

In horses, intravenous dosages of butorphanol ranging from 0.05 to 0.4 mg/kg were shown to be effective in alleviating visceral and superficial pain for at least 4 hours, as illustrated in the following figure:



A definite dosage-response relationship was detected in that butorphanol dosage of 0.1 mg/kg was more effective than 0.05 mg/kg but not different from 0.2 mg/kg in alleviating deep abdominal pain.

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 injection) 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, spasmodic 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.

DOSSAGE

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 lb body weight.

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

Use contents within 4 months of first puncture. 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 injection) Veterinary Injection, 10 mg base activity per mL, 10 mL vials TORBUGESIC (butorphanol tartrate injection) 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

1. Piccio, A.W. *et al.*: "The Pharmacology of Butorphanol" *Arch. Int. Pharmacodyn. Ther.* 220 (2): 231-257, 1976.
2. Dokkin, A.B. *et al.*: "Butorphanol and Pentazocine in Patients with Severe Postoperative Pain" *Clin. Pharmacol. Ther.* 18:547-553, 1975.
3. Gilbert, M.S. *et al.*: "Intramuscular Butorphanol and Meperidine in Postoperative Pain," *Clin. Pharmacol. Ther.* 20: 359-364, 1976.
4. Cavanagh, R.L. *et al.*: "Antitussive Properties of Butorphanol," *Arch. Int. Pharmacodyn. Ther.* 220 (2): 258-268, 1976.
5. Schurig, J.E. *et al.*: "Effect of Butorphanol and Morphine on Pulmonary Mechanics, Arterial Blood Pressure, and Venous Plasma Histamine in the Anesthetized Dog," *Arch. Int. Pharmacodyn. Ther.* 233: 296-304, 1978.
6. Nagashima, H. *et al.*: "Respiratory and Circulatory Effects of Intravenous Butorphanol and Morphine," *Clin. Pharmacol. Ther.* 19: 735-745, 1976.
7. Popio, K.A. *et al.*: "Hemodynamic and Respiratory Effects of Morphine and Butorphanol," *Clin. Pharmacol. Ther.* 23: 281-287, 1978.
8. Robertson, J.T. and Muir, W.W.: "Cardiopulmonary Effects of Butorphanol Tartrate in Horses," *Am. J. Vet. Res.* 42: 41-44, 1981.
9. Kalpravidh, M. *et al.*: "Effects of Butorphanol, Flunixin, Levorphanol, Morphine, Pentazocine and Xylazine in Ponies," *Am. J. Vet. Res.* 45: 217-223, 1984.

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IMPORTANT SAFETY INFORMATION

CARBOCAINE-V

Do not use Carbocaine-V in horses intended for human consumption. Avoid intravenous administration. See full Prescribing Information, attached.

DEPO-MEDROL

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.

DORMOSEDAN GEL

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 gel-dosing syringes with caution to avoid direct exposure to skin, eyes or mouth. See full Prescribing Information, attached.

DORMOSEDAN STERILE SOLUTION

Do not use Dormosedan Sterile Solution in horses with pre-existing atrioventricular (AV) or sinoatrial (SA) block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Intravenous potentiated sulfonamides should not be used in anesthetized or sedated horses. Careful consideration should be given to horses approaching or in endotoxic or traumatic shock, to horses with advanced liver or kidney disease, or to horses under stress from 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.

KETOFEN

Ketofen should not be used in breeding horses. Do not use in horses intended for human consumption. See full Prescribing Information, attached.

TORBUGESIC

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. See full Prescribing Information, attached.

References

1. Zoetis Inc. Data on File. Equine pain and sedation market research.
2. Zoetis Inc. Data on file. Equine brand health study.
3. Modern Veterinary Therapeutics. Detomidine hydrochloride product insert. <http://modernveterinarytherapeutics.com/wp-content/uploads/2021/03/Detomidine-Hydrochloride-Insert-no.pdf>. September 3, 2024.
4. England GC, Clarke KW. Alpha 2 adrenoceptor agonists in the horse—a review. *Br Vet J*. 1996; 152(6):641-657. doi: 10.1016/s0007-1935(96)80118-7.
5. Daunt D. Detomidine in equine sedation and analgesia. *Comp Cont Edu*. 1995;17:1405-1411.
6. Virtanen R, Savola JM, Saano V, et al. Characterization of the selectivity, specificity and potency of medetomidine as an alpha 2-adrenoceptor agonist. *Eur J Pharmacol*. 1988;150(1-2):9-14. doi: 10.1016/0014-2999(88)90744-3.
7. Zeiler GE. A review of clinical approaches to antagonism of alpha2-adrenoreceptor agonists in the horse. *Equine Vet Educ*. 2015;27(1):48-54. doi: 10.1111/eve.12249.
8. Webster A, Pezzanite L, Hendrickson D, et al. Review of intra-articular local anaesthetic administration in horses: clinical indications, cytotoxicity, and outcomes. *Equine Vet J*. 2023;1-14. doi: 10.1111/evj.14027.
9. Carbocaine-V product insert.
10. Owens JG, Kamerling SG, Barker SA. Pharmacokinetics of ketoprofen in healthy horses and those with acute synovitis. *J Vet Pharmacol Ther*. 1995;18(3):187-195. doi: 10.1111/j.1365-2885.1995.tb00577.x
11. Longo E, Autefage A, Bayle R, et al. Efficacy of a nonsteroidal anti-inflammatory, ketofen 10% (ketoprofen) in the treatment of colic in horses. *J Equine Vet Sci*. 1992;12(5):311-315. doi: 10.1136/bmj.38159.639028.7C.
12. Lemonnier LC, Thorin C, Meurice A, et al. Comparison of flunixin meglumine, meloxicam and ketoprofen on mild visceral post-operative pain in horses. *Anim*. 2022;12(526):1-14. doi: 10.3390/ani12040526.
13. Racing Medication and Testing Consortium. RMTc controlled therapeutic substances schedule. rmtcnet.com/wp-content/uploads/2020/12/2020-12-Schedule_CTS_revision-to-clenbuterol-1.pdf. Accessed June 7, 2024.
14. Pearce CJ. Recent developments in equine dentistry. *N Z Vet J*. 2020;68(3):178-186. doi: 10.1080/00480169.2020.1722971.
15. Garrett KS. When radiography and ultrasonography are not enough: the use of computed tomography and magnetic resonance imaging for equine lameness cases. *J Am Vet Med Assoc*. 2022;260(10):1113-1123. doi: 10.2460/javma.22.03.0136.
16. Bonomelli N, Bonilla AG. Standing surgery among equine board certified surgeons: survey regarding current use and trends. *Equine Vet J*. 2023;55(6):1045-1057. doi: 10.1111/evj.13920.



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