**Hydrochloride.** Detomidine hydrochloride is a white, crystalline, The chemical name is 1H imidazole, 4-[(2,3-dimethylphenyl) methyl]-

**For Sedation and Restraint in Horses Only**

Take the syringe out of the horse's mouth, depress the syringe and allow the gel to fall onto the tongue. Do not exceed the recommended label dose.

**Table 1: Sublingual dosing of DORMOSEDAN GEL**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of Horses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>42</td>
</tr>
<tr>
<td>DORMOSEDAN GEL</td>
<td>42</td>
</tr>
</tbody>
</table>

**INDICATIONS:**

For sublingual use in horses only. Do not use in horses intended for breeding, pregnant, or lactating horses. DORMOSEDAN GEL has not been evaluated for use in breeding, pregnant, or lactating horses.

**CONTRAINDICATIONS:**

Do not use in horses with known hypersensitivity to the active ingredient or any of its components. Do not use in horses with pre-existing atrioventricular block, severe cardiac dysfunction, or other cardiovascular abnormalities. Do not use in horses with pre-existing chronic renal failure.

**ADVERSE REACTIONS:**

- Hypotension: Blood pressure may decrease.
- Bradycardia: Heart rate may decrease.
- Sedation: Horses may show sedative effects lasting approximately 90-180 minutes after administration. In general, horses show sedative effects lasting approximately 3 hours after administration. Withhold food and water until the sedative effects of the product wear off.

**Table 2: Adverse reactions (number of horses) during the clinical field study**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Placebo (N=42)</th>
<th>DORMOSEDAN GEL (N=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flatulence</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Facial/oral edema</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Headache</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Ataxia</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Lethargy</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mild ataxia (horse stable but swaying slightly)</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>Severe ataxia (horse unable to stand)</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Nausea</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

**PHARMACOKINETICS:**

Tmax: 30 minutes post dose. Cmax: 0.042 mg/mL by 2.75 mg/mL. Serum half-life: 1-2 hours.

**DOGS:**

Detomidine is indicated for sedation and restraint in dogs. The chemical name is 1H imidazole, 4-[(2,3-dimethylphenyl) methyl]-

**Table 3: Clinical field study**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of Horses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>22</td>
</tr>
<tr>
<td>DORMOSEDAN GEL</td>
<td>22</td>
</tr>
</tbody>
</table>

**CONTRIBUTORS:**

DORMOSEDAN GEL is a trademark of Ceva Sante Animale, a Perrigo Company.
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.

How is Dormosedan Gel administered?

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 be done in an anxious horse.

Before you administer Dormosedan Gel to your horse, you should:
- Consult with your veterinarian.
- Be sure you can provide adequate supervision.
- Ensure that the horse is in a quiet area.
- Provide a quiet environment.

Following appropriate dosing of the gel, your horse should be kept in a quiet area until sedation is achieved. Withhold food and water until the horse has recovered.

What should I expect after administering Dormosedan Gel?

Following appropriate dosing of the gel, your horse should be kept in a quiet area until sedation is achieved. Withhold food and water until the horse has recovered.

During the sedation, you will usually see:
- Salivation
- Slight muscle tremors
- Decreased responsiveness to commands
- Decreased excitement
- Slowed respiration
- Lowered body temperature
- Decreased heart rate
- Decreased blood pressure
- Decreased pain
- Decreased noise
- Decreased defense reaction (for example, kicking)

Do not move the horse around while under the effects of Dormosedan Gel. Do not allow the horse to get up until it is fully sedated. Do not repeat the dose.

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 symptoms that include blindness, breathing difficulty, or choking. If you get the gel in your eyes, rinse them with water for 15 minutes. If you get the gel in your mouth, rinse without swallowing.

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 veterinarian for this information.

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 whether the prescribed drug is provided only as a summary and does not take the place of important information 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 a prescription medicine. It is provided only as a summary and does not take the place of the information from your veterinarian. Contact your veterinarian for this information.

What should I know about Dormosedan Gel?

Dormosedan Gel is an alpha2-adrenoceptor agonist. It is prescribed by veterinarians to allow procedures to be done in an anxious horse. Dormosedan Gel has not been shown to be done in an anxious horse. Dormosedan Gel should only be given to the horse for which it was prescribed. This sheet provides only as a summary and does not take the place of important information 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 should I know about Dormosedan Gel?

Dormosedan Gel is provided only as a summary and does not take the place of the information from your veterinarian. Contact your veterinarian for this information.

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 be done in an anxious horse.

How should the product be handled?

Dormosedan Gel should be handled according to the manufacturer's recommendations. Dormosedan Gel is provided only as a summary and does not take the place of important information 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 should I do if the product is breathed in?

Dormosedan Gel is provided only as a summary and does not take the place of important information 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.

Contact Information

For a copy of the Safety Data Sheet to report adverse reactions, call Zoetis Inc. at 1-888-963-8471. For additional information about Detomidine hydrochloride, contact Zoetis Inc. at 1-888-FDA-VETS or www.fda.gov/reportanimalae. 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.

What 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.

If you have or have had a history of cardiovascular disease (for example, hypertension or heart attack) take special precautions after administration, wear impermeable gloves when performing any tasks that require contact with the horse's mouth.

If the horse appears to be fully sedated, it may take up to 3-4 hours. 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 sedated horses. Handling or any other sudden stimuli, including noise, may cause a defense reaction (for example, kicking) even in sedated horses.

If after 40 minutes there is no sedation, contact your prescribing veterinarian immediately. Accidental exposure could result in the drug affecting the membranes of the mouth, rinse without swallowing. 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 case of accidental eye exposure, flush with water for 15 minutes.

If after 40 minutes there is no 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 have or have had a history of cardiovascular disease (for example, hypertension or heart attack) take special precautions after administration, wear impermeable gloves when performing any tasks that require contact with the horse's mouth.