**INDICATIONS:** DORMOSEDAN GEL is indicated for sedation and restraint in horses. **DOSEAGE AND ADMINISTRATION:** DORMOSEDAN GEL produces sedation when administered sublingually at 0.018 mg/kg (0.040 mg/kg). DORMOSEDAN GEL must be placed beneath the tongue of the horse and is not meant to be swallowed. The dosage syringe delivers the product in the 0.25 mL increments. The following dosing table may be used to determine the correct dose of DORMOSEDAN GEL (Table 1). **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 anaphylactic reactions were reported in 220 horses treated with DORMOSEDAN GEL and 68 horses treated with placebo. **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. This is a crystalline, water-soluble substance having a molecular weight of 222.7. The molecular formula is C₇H₁₈N₄HCl and the structural formula is

![Chemical Structure](image)

**ADVERSE REACTIONS:**

**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 201 horses treated with DORMOSEDAN GEL and in 82 horses treated with placebo:

- 3 horses reported sweating
- 1 horse reported muscle tremors

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

<table>
<thead>
<tr>
<th>Clinical Sign</th>
<th>DORMOSEDAN GEL</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweating</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Muscle tremors</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Epiptora</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Pale mucous membranes</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

In a laboratory study, transient erythema of the mucous membranes was seen in 2 (of 8) horses that received the recommended dose of detomidine gel.

**Clinical Pharmacology:** Detomidine is a potent non-narcotic alpha₂-adrenoceptor agonist which produces sedation with a central effect inhibiting the transmission of noradrenaline-mediated nervous impulses. Blood pressure decreases as a result of a decrease in cardiac output, possibly due to inhibition of insulin release, and increases production of urine 2 to 4 hours after treatment. In some horses, sweating, salivation and slight muscle tremors may be seen. Partial, transient perspiration may occur in stallions and geldings. Because of continued lowering of the head during sedation, mucus discharges from the nose may block the airway. Swallowing of the head, particularly around the eyes, may be seen.

Detomidine is oxidized mainly in the liver. Most metabolites are excreted in the urine. Halflife (T½) is 1-2 hours. Detomidine is rapidly distributed; volume of distribution (Vd) varies between 0.69 L/kg and 1.98L/kg. Protein binding is about 85%. Detomidine is a high extraction ratio drug. Alterations in liver blood flow (the site of detomidine metabolism) can change the rate of drug clearance and consequently, drug exposure. The sedative effects of detomidine (using head droop as a marker for sedation) are highly correlated to blood concentration, regardless of the route of administration.

First pass effect results in a very small portion of drug reaching the systemic circulation if it is swallowed. Sedation achieved with the DORMOSEDAN GEL is attributable to sublingual drug absorption. Peak concentrations occur approximately 1.83 hours after sublingual administration. Sedation achieved with the DORMOSEDAN GEL. The peak concentrations observed after administration of DORMOSEDAN GEL are approximately 40% of those observed after intramuscular injection of detomidine. The absolute bioavailability of detomidine in DORMOSEDAN GEL is 22%.

**EFFECTIVENESS:** A prospective, randomized, masked, multi-center study was conducted to evaluate under field conditions, whether DORMOSEDAN GEL provided sufficient sedation and restraint in horses. Horses were randomly placed on two different behaviors requiring administration of a sedative. Two hundred and seventy-one client-owned horses of any breed or sex were sedated to facilitate grooming (including cleaning of the prepuce), hoof care, floating teeth (manually), palpation of joints, endoscopes, 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. Half the sedated group was treated with 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. The statistical 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

<table>
<thead>
<tr>
<th>Procedure score</th>
<th>DORMOSEDAN GEL N=129</th>
<th>Placebo N=42</th>
</tr>
</thead>
<tbody>
<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 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%), clearing the prepulse (81%), manual floating of teeth (69%), hoof trimming or shoeing (86%), 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/oral discharge, and congestion of oral mucous membranes. Ataxia, sweating, and reversible penile prolapse were observed. Rhymatous mucous membranes were seen at the area of dose application in 2/6 horses. Treatment 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 was 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 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.

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.

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.

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.