

DORMOSEDAN GEL[®]

(detomidine hydrochloride)

Frequently Asked Questions for Horse Owners

I. GENERAL OVERVIEW

What is DORMOSEDAN GEL?

DORMOSEDAN GEL (detomidine hydrochloride) 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.

What is the indication for DORMOSEDAN GEL in horses?

DORMOSEDAN GEL is indicated for sedation and restraint in horses. For example, DORMOSEDAN GEL has been shown effective in procedures such as: clipping, sheath cleaning, hoof trimming and/or shoeing, etc.

What is the mechanism of action of DORMOSEDAN GEL?

Detomidine is a potent non-narcotic alpha₂-adrenoceptor agonist which produces sedation with a central effect inhibiting the transmission of noradrenalin-mediated nervous impulses.

What is the minimum age for DORMOSEDAN GEL?

DORMOSEDAN GEL has not been evaluated in horses younger than one year of age.

II. DOSING AND ADMINISTRATION

What is the dose & route of administration of DORMOSEDAN GEL in horses?

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.

Approximate body weight (lb)	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 - 1099	2.50
1100 - 1209	2.75
1210 - 1320	3.00

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Where should DORMOSEDAN GEL be administered to the horse to be given properly?

DORMOSEDAN GEL must be placed beneath the tongue of the horse and is not meant to be swallowed.

What would happen if my horse spits it out or swallowed part of the dose?

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.

How much effect would DORMOSEDAN GEL have if swallowed?

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.

My horse hates oral meds. Can I mix it with feed?

No. DORMOSEDAN GEL needs to be in contact with sublingual oral mucosa (under the tongue) to allow proper absorption. Mixing it with feed increases the chances of it being swallowed and not being properly absorbed.

What if there is feed in its mouth?

DORMOSEDAN GEL needs to be administered to horses without feed in their mouths or immediate access to water to allow proper absorption via sublingual oral mucosa (under the tongue). Mouths should be cleaned of feed prior to administration of DORMOSEDAN GEL.

My horse is larger than 1300 pounds, how do I dose?

One DORMOSEDAN GEL syringe contains a label dose of 40 mcg/kg for a horse weighing up to 600 kg (1,320 lbs.). For a heavier horse administer additional gel from a second syringe to provide the total label dose calculated for the body weight of the horse.

How long after dosing the horse do I have to wait before it can compete?

It has not been determined how soon prior to a show DORMOSEDAN GEL can be given. Please contact the USEF/FEI, AQHA or other drug testing authority for guidance for shows under their jurisdiction.

III. PRODUCT CHARACTERISTICS

What is the color and consistency of the gel?

DORMOSEDAN GEL has the consistency of a hand sanitizer gel and is blue in color.

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Does the DORMOSEDAN GEL have any taste or odor?

No. DORMOSEDAN GEL is an odorless gel with no flavor additives.

What is the palatability of DORMOSEDAN GEL?

129 horses were dosed with DORMOSEDAN GEL and 125 (97%) accepted the sublingual (under the tongue) dose with mild or no objections.

IV. PRODUCT STORAGE AND HANDLING

What is the best way to store the product?

DORMOSEDAN GEL is a single use veterinary prescription product which when stored at room temperature (68° F- 77° F) will last until expiration date.

What is the shelf life?

The expiration date is 2 years from the date of manufacture.

Is the product sensitive to light?

Yes, DORMOSEDAN GEL should be kept in its original carton until used to protect from direct sunlight.

What is the safety of frozen product or freeze/thaw data?

A freeze-thaw study was performed with the product going through 3 freeze-thaw cycles in a week with no adverse effect on the product or the functionality of the syringe.

What about sensitivity to high temperatures?

Normal shipping and storage precautions should be taken as with all medications needing to be stored at room temperature. In additions, a 6 month stability test was completed successfully for a batch stored at 104° F and 75% relative humidity without any degradation of the product.

Can a partially used syringe be re-used at a later time?

No, there is no data to support the sterility/safety or efficacy of the unused portion. DORMOSEDAN GEL is designed to be used one time at a proper dose prescribed by your veterinarian. The remaining product should be disposed of properly being sure to follow any local requirements for prescribing medications.

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V. EFFICACY

What is the half life of DORMOSEDAN GEL?

Half-life (T_{1/2}) is 1-2 hours.

How long will sedation last?

In general, horses show sedative effects lasting approximately 90-180 minutes.

What will my horse look like when it is sedated? How will it act?

If your horse is properly sedated it should have a lowered head, droopy eyelids and its legs should appear stiff and difficult to move. Horses commonly adopt a “saw horse” stance naturally to balance it when sedated. In addition, a horse’s usual heart rate will be lowered. It will act as if it does not care about its surroundings. Even so, one must be careful as sudden movements and noises will still be able to startle some horses which appear sedated. The most important rule of thumb around a sedated horse is to treat the horse with the same respect as one would as if it was not sedated.

Will my horse fall down?

Sedated horses may sway or lean or hang their heads but it is unlikely it will fall down. Following appropriate dosing 26% were markedly ataxic (wobbly) but none fell down. Additionally, when horses were dosed up to 5 times the appropriate dose no horses were reported to have fallen. After your horse has been administered DORMOSEDAN GEL, let your horse relax and allow its head to slowly drop. Do not attempt to hold the head. In addition let your horse naturally keep its balance being sure not to restrict movement of its head with crossties or movement of its legs with hobbles. Horses commonly adopt a “saw horse” stance naturally to balance itself when sedated.

What do I do if I gave the product and it didn’t seem to work?

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 for further guidance. Do not repeat the dose.

Can my horse feel pain while it is sedated?

DORMOSEDAN GEL has not been shown to provide analgesia and should not be used for painful procedures. DORMOSEDAN GEL should not be used with other sedative drugs because the effects may be additive. Be sure to discuss with your prescribing/attending veterinarian any additional measures necessary for pain management if you think a procedure will hurt your horse.

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How soon after dosing can I feed and water my horse?

All clinical study horses when dosed properly showed normal reactions to stimuli after 4 hours. If however your horse still appears sedated (head down, droopy eyelids, reluctant to move) provide water but do not feed hay or grain until your horse appears normal. (study # 1953C-60-05-203)

VI. SAFETY

Can I use DORMOSEDAN GEL in pregnant mares?

DORMOSEDAN GEL has not been evaluated for use in breeding, pregnant or lactating horses.

Can I vaccinate my horse while it is sedated?

There are no specific contraindications. Recommended to speak to your veterinarian for their recommendation because they know what is best for your horse.

Safe to use in Donkeys and mules?

Data to support safety and efficacy has not been established in donkeys and mules. Please consult your veterinarian.

Can this be used in Miniature Horses?

There is no contraindication for specific breeds of horses.

Can this be used with other sedation products if needed?

DORMOSEDAN GEL should not be used with other sedative drugs because the effects may be additive.

Can this be mixed with other products like a paste dewormer?

No, it is not recommended to physically mix DORMOSEDAN GEL with anything. Safety and efficacy data has not been established to support mixing the product.

Can this be mixed in one syringe with other products?

No, not recommended to physically mix DORMOSEDAN GEL with anything. DORMOSEDAN GEL was designed as a veterinary prescribed, single use, stand alone sedative. Always consult your veterinarian for proper use of DORMOSEDAN GEL to sedate your horse during the process of purchasing a veterinary prescriptive product such as DORMOSEDAN GEL.

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Can this product be used if my horse is on chronic medications? (I.e. NSAIDs, neuroceuticals, herbal supplements, daily anthelmintics, feed-through fly control products, antihistamines, hormone replacement therapy, etc.)

No studies have been conducted in which horses were on known concurrent medications. As with all prescription medications discuss with your attending veterinarian the appropriateness of using DORMOSEDAN GEL for your horse.

Can this be given to my horse if he is showing signs of colic?

DORMOSEDAN GEL is indicated for sedation to facilitate restraint for non-invasive veterinary procedures and minor husbandry procedures only, not for analgesia. A horse exhibiting signs of colic should be examined by a veterinarian before any medication is given.

Can this be used to trailer a horse?

DORMOSEDAN GEL has not been evaluated for this purpose.

Can this be given to spooky horses or hot horses before a trail ride etc..?

It is not recommended to ride a horse that has been sedated with DORMOSEDAN GEL. We have not evaluated it for this purpose and would not recommend doing so. As with all α_2 -adrenoreceptor agonist sedatives (the drug class of DORMOSEDAN GEL), there is the potential for adverse reactions which may include a decreased heart rate and/or respiratory rate and ataxia (wobbling).

What would happen if my dog/cat got a hold of the syringe and ingested some of the product? What do I do?

If you suspect your dog/cat has possibly ingested and/or come in contact with this product please contact your veterinarian immediately. DORMOSEDAN GEL has sedative effects in dogs/cats. Please have the package insert with you when you call your veterinarian and if you need your pet treated. Pet Poison Helpline: 800-213-6680

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VII. USER SAFETY

What should be done if there is human exposure?

Detomidine hydrochloride can be absorbed into the 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, the person exposed should seek immediate medical attention. Accidental exposure could result in the drug affecting the person exposed, causing symptoms that include sleepiness, low blood pressure, and slower heart rate. **DO NOT ALLOW THE EXPOSED PERSON TO DRIVE** because detomidine may cause the person exposed to feel drowsy or sleepy. Share the package information with the health care provider and tell the physician that the product contains an alpha₂-adrenoceptor agonist.

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.

The use of impermeable gloves is recommended when administering DORMOSEDAN GEL. Be sure to have the package insert for DORMOSEDAN GEL present when contacting a healthcare provider.

What should be done if DORMOSEDAN GEL is squirted into one's eye?

Immediately flush the affected eye for 15 minutes. In all cases of accidental exposure, seek medical attention immediately. Be sure to have the package insert for DORMOSEDAN GEL present when contacting a healthcare provider, and tell the physician that the product contains an alpha₂-adrenoceptor agonist.

If a person needs to be examined by a physician please do not attempt to drive but have someone else do this. Do not operate any hazardous machinery or equipment until fully recovered.

What should be done if a child has been exposed to DORMOSEDAN GEL?

DORMOSEDAN GEL, as well as all prescription medications, is to be stored in a safe place away from children. If, however, a child is exposed to DORMOSEDAN GEL, call a local physician immediately being sure to have the package insert present to provide information to the health professional.

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What precautions should be taken if a product handler has a known cardiovascular disease, arrhythmia?

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.

Do I need to wear gloves while using DORMOSEDAN GEL?

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