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Domosedan Gel 7.6mg/ml Oromucosal Gel

Species:	Horses only
Therapeutic indication:	**Pharmaceuticals: Neurological preparations:** Tranquilisers
Active ingredient:	Detomidine Hydrochloride
Product:	Domosedan Gel® 7.6mg/ml Oromucosal Gel
Product index:	Domosedan Gel 7.6mg/ml Oromucosal Gel
Withdrawal notes:	Horses: Meat & offal - Zero Days, Milk - Zero Hours
Incorporating:	

Presentation

A translucent blue oromucosal gel containing detomidine 6.4 mg/ml (equivalent to detomidine hydrochloride 7.6 mg/ml)

Uses

Target species: Horses

Sedation of horses to facilitate restraint for non-invasive veterinary procedures (e.g. passage of naso-gastric tube, radiography, rasping teeth) and minor husbandry procedures (e.g. clipping, shoeing).

Dosage and administration

Target species: Horses

The product is administered sublingually at 40 mcg/kg. The dosing syringe delivers the product in 0.25 ml increments. The following dosing table provides the dose volume to be administered for the corresponding body weight in 0.25 ml increments.

Approximate body weight (kg)	Dose volume (ml)
150 - 199	1.00
200 - 249	1.25
250 - 299	1.50
300 - 349	1.75
350 - 399	2.00
400 - 449	2.25
450 - 499	2.50
500 - 549	2.75
550 - 600	3.00

Instructions for dosing: Apply impermeable gloves and remove the syringe from the outer carton. While holding the plunger, turn the ring-stop on the plunger until the ring is able to slide freely up and down the plunger. Position the ring in such a way that the side nearest the barrel is at the desired volume marking. Turn the ring to secure it in place.

Make sure that the horse's mouth contains no feed. Remove the cap from the tip of the syringe and save the cap for replacement. Insert the syringe tip into the horse's mouth from the side of the mouth, placing the syringe tip beneath the tongue at the level of the corner of the mouth. Depress the plunger until the ring-stop contacts the barrel, depositing the product under the tongue.

Take the syringe out of the horse's mouth, recap the syringe and return it to the outer carton for disposal. Syringes should be used only once - partially used syringes must be discarded. Remove and discard gloves or wash them in copious quantities of running water.

After administration of the product, the animal should be allowed to rest in a quiet place for approximately 30 - 40 minutes to allow sedation to fully develop before any procedure is initiated.

Should there be a substantial misdosing or swallowing of the product (e.g. the horse spits out or swallows more than an estimated 25% of administered dose), immediate replacement dosing of the lost portion should be attempted with care to avoid accidental overdosing. For animals in which the administered dose results in inadequate duration of sedation to complete the intended procedure, re-administration of the product during the procedure may not be practical since transmucosal absorption is too slow to top-up the sedation. In such cases, a lip twitch may facilitate restraint. Alternatively, a veterinarian can administer additional injectable sedatives according to their clinical discretion.

Contra-indications, warnings, etc

Do not use in seriously ill animals with heart failure or impaired liver or kidney function.

Do not use in conjunction with intravenous potentiated sulphonamides.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

In the absence of compatibility studies, Domosedan Gel must not be mixed with other veterinary medicinal products.

Special warnings

Unlike most other oral veterinary products, this product is not meant to be swallowed. Instead, it must be placed under the tongue of the horse. When the product is administered, the animal should be allowed to rest in a quiet place. Before any procedure is initiated, sedation should be allowed to fully develop (approximately 30 - 40 min).

Special precautions for use in animals

Horses approaching or in endotoxic or traumatic shock, or horses suffering from cardiac diseases, advanced lung disease, or fever should only be treated according to the benefit risk assessment by the responsible veterinarian. Protect treated horses from extreme temperatures. Some horses, although apparently deeply sedated, may still respond to external stimuli.

Food and water should be withheld until the sedative effect of the product has worn off.

Other precautions

The syringe may be used only once. Partially used syringes must be discarded

Adverse reactions

All alpha-2 adrenoceptor agonists, including detomidine, may cause decreased heart rate, changes in the conductivity of cardiac muscle (as evidenced by partial atrioventricular and sinoauricular blocks), changes in the respiratory rate, incoordination/ataxia and sweating. A diuretic effect may be observed 2 to 4 hours after treatment. The potential for isolated cases of hypersensitivity exists, including paradoxical response (excitation). Because of continued lowering of the head during sedation, mucus discharges from the nose and, occasionally, oedema of the head and face may be seen. Partial, transient penis prolapse may occur in stallions and geldings. In rare cases, horses may show signs of mild colic following the administration of alpha-2 adrenoceptor agonists because substances of this class inhibit intestinal motility.

In studies with the product, the following adverse reactions have also been observed: transient erythema at the dose application site, piloerection, oedema of the tongue, hypersalivation, increased urination, flatulence, epiphora, allergic oedema, muscle tremors, and pale mucous membranes.

Use during pregnancy or lactation

Pregnancy:

Use only according to the benefit/risk assessment by the responsible veterinarian. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Lactation:

Detomidine is excreted in trace amounts into the milk. Use according to the benefit/risk assessment by the responsible veterinarian.

Fertility:

The safety of the product has not been investigated in breeding horses.

Interaction with other medicinal products and others forms of interaction

Detomidine potentiates the effect of other sedatives and anaesthetics. Intravenous potentiated sulphonamides should not be used in anaesthetized or sedated animals as potentially fatal dysrhythmias may occur.

Overdose

Overdosage is mainly manifested by delayed recovery from sedation. If recovery is delayed it should be ensured that the animal can recover in a quiet and warm place.

The effects of detomidine can be eliminated using a specific antidote, atipamezole, an alpha-2 adrenoceptor antagonist.

Operator warnings

Detomidine is an alpha-2 adrenoceptor agonist, which may cause sedation, somnolence, decreased blood pressure and decreased heart rate in humans.

Product residues may be present on the barrel and plunger of the oral dosage syringe, or on the lips of horses, after sublingual administration.

The product may cause local skin irritation following prolonged skin contact. Avoid contact with mucosal membranes and skin. Impermeable gloves should be worn to prevent skin contact. As the syringe may be smeared with the product after application, the syringe should be carefully re-capped and returned into the outer carton for disposal. In the case of exposure, wash exposed skin and/or mucous membranes immediately and thoroughly.

Avoid contact with eyes and in the event of accidental contact, rinse abundantly with fresh water. If symptoms occur, seek advice of a physician.

Pregnant women should avoid contact with the product. Uterine contractions and decreased foetal blood pressure may occur after systemic exposure to detomidine.

In case of accidental oral intake or prolonged mucosal contact, seek medical advice and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Advice to doctors: Detomidine is an alpha-2 adrenoceptor agonist intended for animal use only. Symptoms reported after accidental human exposure have included drowsiness, hypotension, hypertension, bradycardia, tingling sensation, numbness,

pain, headache, somnolence, dilated pupils, and vomiting. Treatment should be supportive with appropriate intensive therapy.

Withdrawal period

Meat and offal: Zero days

Milk: Zero hours

Pharmaceutical precautions

For animal use only.

Keep out of the reach and sight of children.

Keep the syringe in the outer carton to protect from light.

Any unused product or waste materials should be disposed of in accordance with local requirements.

Legal category

Legal category: POM-V

Packaging quantities

1 x 3.0 ml pre-filled single-dose syringe in an outer carton (1 syringe per carton)

Further information

The active substance of the product is detomidine. Detomidine is an alpha-2 adrenoceptor agonist with a central effect inhibiting the transmission of noradrenalin-mediated nervous impulses. In the animal, the level of consciousness is lowered and the pain threshold is increased. The duration and level of sedation are dose dependent. In the studies conducted with the recommended 40 mcg/kg dose of the gel, the time to onset of sedation has been approximately 30-40 min and the duration of sedation 2 to 3 hours.

Further information is available in the Summary of Product Characteristics

Marketing Authorisation Holder (if different from distributor)

Orion Corporation

Orionintie 1

02200 Espoo

Finland

Marketing Authorisation Number

UK: Vm 06043/4001

Significant changes

GTIN

GTIN description: DOMOSEDAN GEL 7.5MG/ML 3ML

GTIN: 05012674902134