1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domosedan Gel 7.6 mg/ml oromucosal gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Detomidine 6.4 mg
(equivalent to detomidine hydrochloride 7.6 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Brilliant Blue FCF (E133)	0.032 mg
Hydroxypropylcellulose	
Propylene glycol	
Sodium laurilsulfate	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid, dilute (for pH adjustment)	
Purified water	

Even, translucent, blue gel.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Sedation 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).

3.3 Contraindications

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 cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Unlike most other oral veterinary medicinal products, this veterinary medicinal product is not meant to be swallowed. Instead, it must be placed under the tongue of the horse. When the veterinary medicinal 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 min).

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product has worn off.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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

Veterinary medicinal 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 veterinary medicinal product may cause local skin irritation following prolonged skin contact. Avoid contact with mucosal membranes and skin. Personal protective equipment consisting of impermeable gloves should be worn to prevent skin contact. As the syringe may be smeared with the veterinary medicinal 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 veterinary medicinal 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.

To the physician:
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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

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

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Ataxia
Common (1 to 10 animals / 100 animals treated):	Heart block[1] Hypersalivation Nasal discharge[4] Increased urination[5] Penile prolapse[6] Increased sweating Piloerection
Uncommon (1 to 10 animals / 1 000 animals treated):	Epiphora Flatulence Tongue oedema Allergic oedema Oedema[2,3] Muscle tremor
Rare (1 to 10 animals / 10 000 animals treated):	Colic[7]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Application site erythema[8] Bradycardia Hypersensitivity reaction Hyperventilation Respiratory depression Excitation Pale mucous membrane

[1]resulting from changes in the conductivity of cardiac muscle
[2]due to continued lowering of the head during sedation
[3] of head and face
[4]due to continued lowering of the head during sedation
[5]may be observed 2 to 4 hours after treatment
[6]partial, transient, in stallions and geldings
[7]mild, due to inhibition of intestinal motility
[8]transient

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy and lactation

Pregnancy:
Use only accordingly 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.

3.8 Interaction with other medicinal products and other 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.

3.9 Administration routes and dosage

Sublingual use.
The veterinary medicinal product is administered sublingually at 40 µg/kg. The dosing syringe delivers the veterinary medicinal 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 for cap 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 veterinary medicinal 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. Remove and discard gloves or wash them in copious quantities of running water.

Should there be a substantial misdosing or swallowing of the veterinary medicinal 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Meat and offal: Zero days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QN05 CM90.

4.2 Pharmacodynamics

The active substance of the veterinary medicinal product is detomidine. Its chemical structure is 4-(2,3-dimethylbenzyl) imidazole hydrochloride. 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 µg/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. With detomidine administration, heart rate is decreased. A transient change in the conductivity of the cardiac muscle may occur, as evidenced by partial atrioventicular and sinoauricular blocks. Respiratory rate is slightly decreased. In some horses, sweating, salivation and slight muscle tremors may be seen. Partial, transient penis prolapse may occur in stallions and geldings. Blood glucose concentration may be temporally increased.

4.3 Pharmacokinetics

At a dose of 40 µg/kg of the veterinary medicinal product, the mean C_{max} was 4.3 ng/ml and mean t_{max} was 1.83 hours (range from 1 to 3 hours). Following sublingual administration, clinical signs of sedation were evident at approximately 30 minutes after dosing.

The bioavailability of detomidine administered as the sublingual gel in the horse is about 22 %. If the veterinary medicinal product is swallowed the bioavailability is significantly decreased.

Elimination of detomidine occurs by metabolism with a half-life of about 1.25 hours. Metabolites of the drug are eliminated mainly in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Keep the syringe in the outer carton in order to protect from light. The syringe may be used only once. Partly used syringes must be discarded.

5.4 Nature and composition of immediate packaging

Pre-filled, single-dose syringe enabling doses from 1.0 to 3.0 ml are packed in an outer carton. Pre-filled syringes consist of a syringe barrel (HDPE), cap (LDPE), plunger (HDPE) and locking ring.

Package sizes: 1 x 3.0 ml (1 syringe per carton)

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

VPA10664/001/001

8. DATE OF FIRST AUTHORISATION

27/02/2009

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

08/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).