PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domosedan Gel 7.6 mg/ml oromucosal gel

2. STATEMENT OF ACTIVE SUBSTANCES

1ml contains detomidine hydrochloride 7.6 mg

3. PACKAGE SIZE

3 ml

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Sublingual use.

Dosage table:

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

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days
Milk: Zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

14. MARKETING AUTHORISATION NUMBERS

Vm 06043/4001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domosedan Gel

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Detomidine hydrochloride 7.6 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Domosedan Gel 7.6 mg/ml oromucosal gel

2. Composition

Each ml contains:

Active substance:
Detomidine 6.4 mg
(equivalent to detomidine hydrochloride 7.6 mg)
Excipient:
Brilliant Blue FCF (E133) 0.032 mg
Even, translucent, blue gel

3. Target species

Horses.

4. Indications for use

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).

5. 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 case of hypersensitivity to the active substance or to any of the excipients.

6. Special Warnings

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).

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.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.
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.
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.
Interaction with other veterinary 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.
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.
Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
Special restrictions for use and special conditions for use:
Not applicable

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first

instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

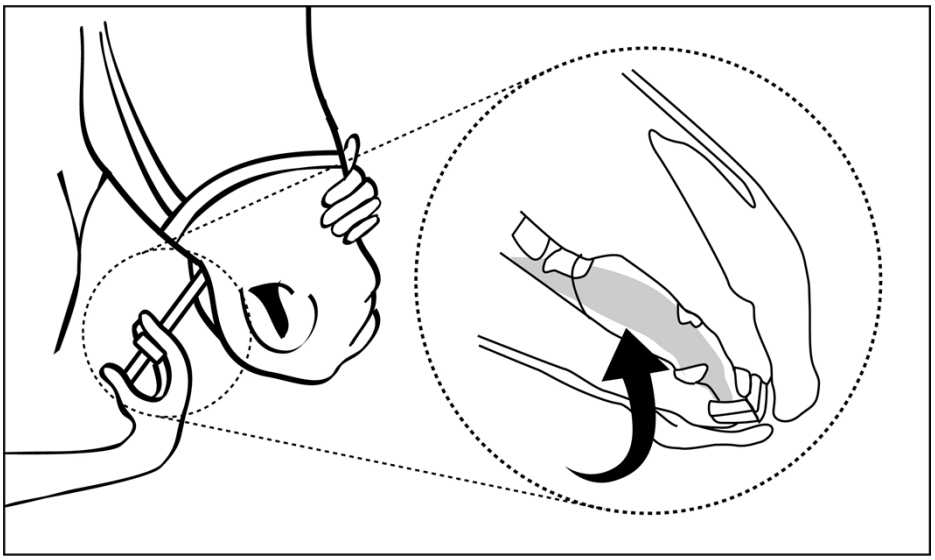
Sublingual use.
The veterinary medicinal is administered sublingually at 40 µg/kg. The dosing syringe delivers the veterinary medicinal product in 0.25 ml increments. The following dosing table provides the dose volume to be administered for the corresponding body weight in 0.25 ml increments.

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

9. Advice on correct administration

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.

The following picture demonstrates the correct administration.



The veterinary medicinal product is administered 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.

10. Withdrawal periods

Meat and offal: Zero days
Milk: Zero hours

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the syringe in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the syringe label and outer carton after Exp. The expiry date refers to the last day of that month.
The syringe may only be used once. Part used syringes must be discarded.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06043/4001
Package sizes: 1 x 3.0 ml (1 syringe per carton)

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:
Orion Corporation
Tengströminkatu 8
FI-20360 Turku
Finland

Local representatives and contact details to report suspected adverse reactions:
Distributed by:
Vetoquinol UK Limited
Steadings Barn,
Pury Hill Business Park,
Nr Alderton,
Towcester,
Northants,
NN12 7LS

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall

Approved: 01 August 2025