PARTICULARS TO APPEAR ON THE OUTER CARTON LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domosedan Gel 7.6 mg/ml Oromucosal Gel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains
detomidine hydrochloride 7.6 mg

3. PHARMACEUTICAL FORM

Oromucosal gel

4. PACKAGE SIZE

3 ml

5. TARGET SPECIES

Horse

6. INDICATIONS

-

7. METHOD AND ROUTE OF ADMINISTRATION

Sublingual use.
Read the package leaflet before 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

8. WITHDRAWAL PERIOD

Meat and offal: Zero days
Milk: Zero hours

9. SPECIAL WARNINGS

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation,
Orionintie 1
FI - 02200 Espoo
Finland

16. MARKETING AUTHORISATION NUMBER

Vm 06043/4001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOMOSEDAN GEL 7.6 mg/ml oromucosal gel

2. QUANTITY OF THE ACTIVE SUBSTANCE

-

3. CONTENTS BY VOLUME

3 ml

4. ROUTE OF ADMINISTRATION

Sublingual use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:

DOMOSEDAN GEL 7.6 mg/ml oromucosal gel

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOMOSEDAN GEL 7.6 mg/ml oromucosal gel

detomidine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

DOMOSEDAN GEL 7.6 mg/ml oromucosal gel is an even, translucent, blue gel containing 7.6 mg/ml detomidine hydrochloride (active substance).

Other ingredient: Brilliant Blue FCF (E133)

4. INDICATIONS

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. 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse

8. DOSAGE, ROUTE AND METHOD OF ADMINISTRATION

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

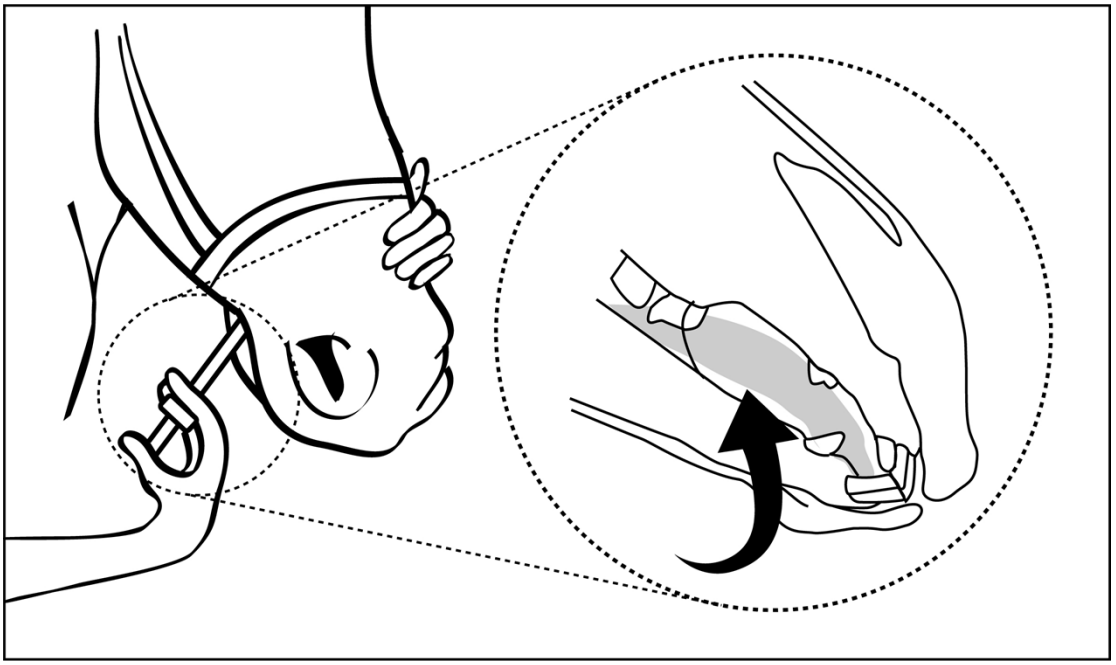
9. ADVICE ON CORRECT ADMINISTRATION

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 product under the tongue.

The following picture demonstrates the correct administration.



DOMOSEDAN GEL 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 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.

10. WITHDRAWAL PERIOD

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 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 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 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.

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.

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.

Other precautions:

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

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.

Interactions 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.

Overdose (symptoms, emergency, procedures, 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.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2019

15. OTHER INFORMATION

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

Distributed by:

Vetoquinol UK Limited
Steadings Barn,
Pury Hill Business Park
Nr. Alderton
Towcester
Northants
NN12 7LS

Vétoquinol-logo

Orion Pharma-logo

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

Approved: 10 May 2019