Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Domosedan 10 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Detomidine hydrochloride 10 mg/ml

Excipients:
Methyl parahydroxybenzoate (E 218) 1 mg/ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

The product is a sedative with analgesic properties used to facilitate handling of horses for examination, minor surgical interventions and other manipulations.

The product can be used in combination with butorphanol.
The product is also indicated for use with ketamine for short duration general anaesthesia to carry out surgical procedures such as castration.

4.3 Contraindications

Do not administer to horses during pregnancy.
Do not use in conjunction with sympathomimetic amines, such as adrenaline, dobutamine and ephedrine, or with intravenous potentiated sulphonamides.
Do not use in horses with pre-existing atrio-ventricular heart blocks, with severe cardiac insufficiency, respiratory disease or chronic renal failure.
Do not use the butorphanol combination in horses suffering from colic.
Domosedan/butorphanol combination should not be used in horses with a history of liver disease or cardiac irregularities.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Careful consideration should be given prior to administration to animals in shock and to animals with liver or kidney disease, fever or to animals under extreme stress. Protect treated animals from extreme temperatures.

When the veterinary medicinal product is administered, the animal should be allowed to rest in a maximally quiet place. Before any procedure is initiated, the sedation should be allowed to reach its peak. This takes about 10 minutes. At the onset of the effect it is to be noted, that the animal may stagger and drop its head.
Intravenous administration should be slow.
It is recommended that feed should be withheld for at least 12 hours prior to anaesthesia.
The horse should not be given water or feed before the drug effect has passed.
It is always necessary to administer the product prior to ketamine and allow sufficient time (5 minutes) for sedation to develop. The two agents must therefore never be administered simultaneously in the same syringe.
Intravenous potentiated sulphonamides should not be used in anaesthetised or sedated animals as potentially fatal dysrhythmias may occur.
Some horses, although apparently deeply sedated, may still respond to external stimuli.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Avoid skin, eye or mucosal contact.
Immediately after exposure, wash the exposed skin with large amounts of fresh water.
Remove contaminated clothes that are in direct contact with the skin.
In the case of accidental contact of the product with eyes rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor.
If pregnant women handle the product, special caution should be observed not to self inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

To the physician:
Detomidine hydrochloride is an alpha-2 adrenoreceptor agonist. Symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

4.6 Adverse reactions (frequency and seriousness)

The following adverse reactions are very rare (< 1/10,000):
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
- urticaria
- sweating
- isolated cases of hypersensitivity, including paradoxical response (excitation)
- a diuretic effect may be observed 45 to 60 minutes after treatment
- mucus discharges from the nose and, occasionally, oedema of the head and face may be seen because of continued lowering of the head during sedation
- partial, transient penis prolapse in stallions and geldings

In rare cases, horses may show signs of mild colic, because substances of this class inhibit intestinal motility.

Mild adverse reactions have reportedly resolved uneventfully without treatment. Adverse reactions should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
The product should not be used in mares during pregnancy.

Lactation:
No studies have been conducted in mares; trace amounts of detomidine have been found in milk of cows treated with the product.

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

4.8 Interaction with other medicinal products and other forms of interactions

The product should be used with care with other sedatives and anaesthetics because of an additive/synergistic effect.
Where appropriate the product may be used in conjunction with local anaesthetic agents.
Induction of anaesthesia with the product and ketamine has been used prior to maintenance with halothane. Because of the nature of the induction agents, the effects of halothane may be delayed and special care must be taken to avoid over-dosage.
When the product is used as a premedication prior to general anaesthesia, the product may delay onset of induction.The use of the product in conjunction with sympathomimetic amines such as adrenaline, dobutamine and ephedrine is contraindicated.
The concurrent use of certain intravenous potentiated sulphonamides may cause cardiac arrhythmia with fatal outcome. Do not use in combination with intravenous potentiated sulphonamides.

4.9 Amounts to be administered and administration route

The following procedures are recommended. Use two sterile needles, one to fill the syringe from the bottle and one to inject the patient. Once the required dose has been withdrawn from the vial, the syringe should be removed from the needle. A separate sterile needle should be inserted into the injection site and the syringe connected to it. The needles should be discarded.

Domosedan

To be administered intramuscularly or by slow intravenous injection at a dose of 10-80 µg/kg depending on the degree of sedation required.

Domosedan/butorphanol for sedation

Dosage: 0.1 ml Domosedan/100 kg (10 µg/kg detomidine hydrochloride) intravenously, followed within 5 minutes by a dose rate in the region of 25 µg/kg butorphanol intravenously. Clinical experience has shown that 5 mg (0.5 ml) Domosedan and 10 mg butorphanol affords effective, safe sedation in horses above 200 kg bodyweight.

Domosedan/ketamine (short duration anaesthesia)

Ketamine must not be used as the sole anaesthetic agent in horses. It is important that, to obtain satisfactory surgical anaesthesia the following procedure is followed. Administer Domosedan at a dose rate of 20 µg/kg by slow intravenous injection. Allow 5 minutes for the horse to become deeply sedated and then administer ketamine at a dose rate of 2.2 mg/kg as an intravenous bolus.
Onset of anaesthesia is gradual, the horse taking approximately 1 minute to become recumbent. In large fit horses recumbency may take up to 3 minutes.

Anaesthesia will continue to deepen for a further 1-2 minutes and during this time the horse should be left quietly. Horses regain sternal recumbency approximately 20 minutes post ketamine administration.

The duration of surgical anaesthesia is approximately 10-15 minutes. The horse should be allowed to stand in its own time. The horse may be ataxic if it stands prematurely and therefore it should be encouraged to remain recumbent.
To facilitate handling and the administration of the induction agents, some horses have received acepromazine by intramuscular injection at a dose rate of 0.03 mg/kg at least 45 minutes before induction of anaesthesia.

Excitable horses are sometimes poor subjects for anaesthesia. It is a prime requisite that the horse should be quietly and carefully handled during the administration of the anaesthetic agents so as to ensure the minimum amount of upset during the induction period. If the horse fails to become sedated following the injection of Domosedan, then ketamine should not be injected and the anaesthetic procedure should be abandoned.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdosage is mainly manifested by delayed recovery from sedation or anaesthesia. In a few individual cases circulatory and respiratory depression may occur.
If recovery is delayed, it should be ensured that the animal can recover in a quiet and warm place. Oxygen supplementation may be indicated in cases of circulatory and respiratory depression.
In cases of overdose, or should the effects of the product become life-threatening, an alpha-2 antagonist (atipamezole) is recommended (2-10 times the dose of detomidine in µg/kg, administer a quarter to a third of the dose initially, followed by the same aliquot dose 5–10 min later until an acceptable clinical response is achieved).

4.11 Withdrawal period(s)

Meat and offal: 1 day

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Psycholeptics; Other hypnotics and sedatives; detomidine.
ATCvet code: QN05CM90

5.1 Pharmacodynamic properties

The active substance of this 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 and analgesia are dose-dependent. With detomidine administration, heart rate is decreased, blood pressure is initially elevated, and then a steady decline to normal is seen. A transient change in the conductivity of the cardiac muscle may occur, as evidenced by partial atrioventricular (AV) and sinoauricular (SA) blocks. Respiratory responses include an initial slowing of respiration within a few seconds to 1-2 minutes after administration, increasing to normal within 5 minutes. Especially at high doses, sweating, piloerection, salivation and slight muscle tremors are frequently seen. Partial, transient penis prolapse may occur in stallions and geldings. Blood sugar concentration is increased.

5.2 Pharmacokinetic particulars

Detomidine is rapidly absorbed after intramuscular injection.The rapid distribution to tissues is followed by almost complete metabolism.The metabolites are mainly excreted in urine and faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Sodium chloride
Water for injections

6.2 Major incompatibilities

The product must not be mixed with other products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

a) Pack sizes: 5 ml and 20 ml
b) Containers: colourless glass type I vial
c) Closures: red rubber chlorobutyl bung with aluminium overseal
d) Content: clear colourless sterile aqueous solution

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10664/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 2000
Date of last renewal: 30 September 2010

10 DATE OF REVISION OF THE TEXT

September 2021