

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

DETOGESIC 10 mg/ml Solution for Injection for Horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Detomidine hydrochloride 10 mg/ml (Detomidine 8.36 mg/ml)

Excipient(s):

Preservative

Methyl parahydroxybenzoate (E218) 1 mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection.

Clear, almost colourless solution for intravenous injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horse.

4.2 Indications for use, specifying the target species

For the sedation and slight analgesia of horses, to facilitate physical examinations and treatments, such as minor surgical interventions.

The product can be used for:

- Medical examinations (e.g. endoscopic, rectal and gynaecological examinations, X-rays)
- Minor surgical procedures (e.g. treatment of wounds, dental treatment, tendon treatment, excision of skin tumours, teat treatment)
- Before treatment and medication (e.g. stomach tube, horse shoeing)

For premedication prior to administration of injection or inhalation anaesthetics.

See section 4.5 before use.

4.3 Contraindications

Do not use in animals with cardiac abnormalities or respiratory disease.

Do not use in animals with liver insufficiency or renal failure.

Do not use in animals with general health problems (e. g. dehydrated animals).

Do not use in the last 3 months of pregnancy.

Do not use in combination with butorphanol in horses suffering from colic.

Do not use in combination with butorphanol in pregnant mares.

See also Sections 4.7 and 4.8.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

As sedation begins, horses may start to sway and lower the head rapidly while they remain standing. To prevent injuries in horse and people while treating horses, the location for treatment should be chosen carefully. Usual precautionary measures should be taken to prevent self-injury.

Animals suffering from shock or liver or kidney disease should only be treated according to the benefit/risk assessment by the responsible veterinary surgeon. The product should not be used in animals suffering from cardiac diseases (with pre-existing bradycardia and risk of atrioventricular block), respiratory, liver or renal insufficiencies or any other extraordinary stress conditions.

It is recommended that feed should be withheld for at least 12 hours prior to anaesthesia.

Water or food should not be offered to treated animals until the drug effect has passed.

In painful procedures detomidine should be used only in combination with an analgesic or a local anaesthetic.

While waiting for the onset of sedation, animals should remain in calm surroundings.

Detomidine/butorphanol combinations should not be used in horses with a history of liver disease or cardiac irregularities.

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

This product should be administered with caution, and care taken to avoid accidental self-injection.

- In the 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.
- Wash the exposed skin immediately after exposure with large amounts of fresh water.
- Remove contaminated clothes that are in direct contact with skin.
- In the case of accidental contact of the product with eyes, rinse abundantly with 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.

Advice to doctors:

Detomidine 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)

Injection of detomidine may cause the following side effects:

- Bradycardia.
- Transient hypo- or hypertension.
- Respiratory depression, rarely hyperventilation.
- Increase in blood glucose.
- As with other sedatives, in rare cases paradoxical reactions (excitations) can develop.
- Ataxia.
- Cardiac arrhythmia, atrioventricular and sino-atrial block.
- Uterine contractions.

At doses above 40 mcg/kg bodyweight, the following symptoms can also be observed: sweating, pilo-erection and tremor of muscles, transient penis prolapse in stallions and geldings.

In very rare cases horses may show mild symptoms of colic following administration of alpha-2 sympathomimetics because substances of this class transiently inhibit the motility of the intestines. The product should be prescribed with caution in horses which present with signs of colic or impaction.

A diuretic effect is usually observed within 45 to 60 minutes after treatment.

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

Do not use the product in mares in the last 3 months of pregnancy. During the remaining months, use only according to a risk/benefit analysis by the responsible veterinary surgeon.

Use during lactation should also be the subject of risk/benefit analysis by the responsible veterinary surgeon.

Do not use in combination with butorphanol in pregnant mares.

4.8 Interaction with other medicinal products and other forms of interactions

Concurrent use of other sedatives should proceed only after consultation of the warnings and precautions for the product(s) concerned.

Detomidine should not be used in combination with sympathomimetic amines such as adrenaline, dobutamine and ephedrine, except as required in anaesthetic emergencies.

The concurrent use of certain potentiated sulphonamides may cause cardiac arrhythmia with fatal outcome. Do not use in combination with sulphonamides.

Detomidine in combination with other sedatives and anaesthetics should be used carefully because additive/synergistic effects may be possible. Where anaesthesia is induced with a combination of detomidine and ketamine, prior to maintenance with halothane, the effects of halothane may be delayed and care must be taken to avoid overdosage. When detomidine is used as a premedicant prior to general anaesthesia, it may delay the onset of induction.

4.9 Amounts to be administered and administration route

Administration route

For intravenous (IV) use only. The product should be injected slowly. Onset of effect is more rapid following intravenous use.

Amount(s) to be administered

Use alone for sedation: dosage table

| Dosage in mcg/kg | Dosage in ml/100 kg | Level of sedation | Commencement of effect (min) | Duration of effect (hrs) |
|---------------------|------------------------|----------------------|---------------------------------|-----------------------------|
| 10-20 | 0.1-0.2 | Light | 3-5 | 0.5-1 |
| 20-40 | 0.2-0.4 | Moderate | 3-5 | 0.5-1 |

When prolonged sedation and analgesia is required, doses of 40 to 80 mcg/kg can be used. The duration of effect is up to 3 hours. It is recommended to wait 15 minutes after detomidine administration before starting the planned procedure.

For combination with other products to intensify sedation or for premedication prior to general anaesthesia, doses of 10 to 30 mcg/kg can be used. Prior to use in combination with other products such as butorphanol or ketamine, consult the appropriate product details for dose rates. Allow 5 minutes after the administration of detomidine for the horse to become deeply sedated before any subsequent treatment.

The bodyweight of the animal to be treated should be determined as accurately as possible to avoid overdosing.

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

Overdose may cause cardiac arrhythmia, hypotension, delayed recovery, and deep depression of the central nervous system and the respiratory system. If recovery is delayed, it should be ensured that the animal can recover in a quiet and warm place. An oxygen supplement may be indicated in circulatory and respiratory depression. In cases of overdose, or should the effects become life-threatening, an alpha-2 antagonist (atipamezole) is recommended (5-10 times the dose of detomidine in mcg/kg).

4.11 Withdrawal period(s)

Meat and offal: 2 days.

Milk: 12 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmcotherapeutic group: Sedative and analgesic

ATC vet code: QN05 CM90

5.1 Pharmacodynamic properties

The active ingredient of the product is 4-(2,3-dimethylbenzyl)-imidazole-hydrochloride (INN: detomidine). Detomidine leads to sedation of treated animals and relieves pain, with duration and intensity of effect being dose related. Detomidine acts as an agonist at alpha-2 adrenoceptors, and observed analgesic effects are due to inhibition of transmission of the pain impulse within the CNS.

Detomidine acts on peripheral alpha-adrenoceptors, therefore an increase in blood glucose level and, at higher dosages, piloerection, sweating and diuresis may occur. An initial increase in mean blood pressure is observed, which returns to normal or slightly below and heart rate decreases. The ECG shows an enlarged PR-interval, and mild atrio-ventricular blocks may be observed. These changes are transient. Respiratory response includes an initial decrease in respiration rate, increasing to normal or slightly higher values within a few minutes.

5.2 Pharmacokinetic particulars

Detomidine is absorbed rapidly after intramuscular injection, with a T_{max} of 15-30 minutes. Bioavailability after intramuscular administration is 66-85 %. After rapid distribution of detomidine into the tissues, with a half life of 0.15 hours post intravenous injection, detomidine is almost completely metabolized, mainly in the liver - $t_{1/2}$ is 1 to 2 hours. The volume of distribution ranges from 0.75 to 1.89 l/kg, and protein binding is 75-85 %. The elimination half life in the horse was 1.19 hours, with less than 1 % parent compound present in urine. Metabolites are mainly excreted via urine and faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)

Sodium chloride

Sodium hydroxide (for pH adjustment)

Water for Injections

6.2 Major incompatibilities

This veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

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

Shelf-life after first opening the container: 28 days.

6.4 Special precautions for storage

Do not store above 25 °C.

Store in the original carton in order to protect from light.

Store in a dry place.

6.5 Nature and composition of immediate packaging

1) Multidose, clear, Type I glass injection vial containing 10 ml solution which may be closed with either a red bromobutyl rubber stopper or grey chlorobutyl rubber stopper, secured with an aluminium crimp.

2) Multidose, clear, cyclic olefin copolymer injection vial containing 15 ml solution, which may be closed with either a red bromobutyl rubber stopper or grey chlorobutyl rubber stopper, secured with an aluminium crimp.

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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Vetcare Limited
PO Box 99
24101 Salo
Finland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10789/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 August 2008

Date of last renewal: 26 April 2013

10 DATE OF REVISION OF THE TEXT

September 2019