PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Presedine 10 mg/ml Solution for Injection for Horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Detomidine hydrochloride 10.0 mg/ml

(equivalent to 8.36 mg/ml detomidine)

3. PACKAGE SIZE

5 ml
10 ml
20 ml

4. TARGET SPECIES

Horses

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

IM or IV

7. WITHDRAWAL PERIODS

Horses (meat and offal): 1 Day

8. EXPIRY DATE

Exp

Once broached use within 28 days. Use by __/__

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDE

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5019

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

User warnings:

Alpha 2-adrenoreceptor agonist can cause severe adverse reactions. You must read the warnings on the package leaflet before using this product.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** *[Distribution category]*

POM-V (‘To be supplied only on veterinary prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {GLASS VIAL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Presedine 10 mg/ml Solution for Injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Detomidine hydrochloride 10.0 mg/ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

EXP

Once broached use within 28 days. Use by __/__

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml

10 ml

20 ml

6. ROUTE(S) OF ADMINISTRATION

IV or IM

7. WITHDRAWAL PERIOD

Horses (meat and offal): 1 Day

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Presedine 10 mg/ml Solution for Injection for Horses

2. COMPOSITION

Active ingredient:

Detomidine hydrochloride (equivalent to 8.36 mg/ml detomidine)	10 mg/ml

Excipients:

Methyl parahydroxybenzoate (E 218)	1 mg/ml

3. TARGET SPECIES

Horses

4. INDICATIONS FOR USE

A sedative with analgesic properties used to facilitate handling of horses for examination, minor surgical interventions and other manipulations. It can be used with or without butorphanol.

The product is also indicated for use with ketamine for short duration general anaesthesia to carry out surgical procedures such as castration.

5. CONTRAINDICATIONS

Do not use in conjunction with sympathomimetic amines or with intravenous potentiated sulphonamides.

Do not administer simultaneously with ketamine in the same syringe (see sections 6 and 8).

Do not use the butorphanol combination in horses suffering from colic. Do not use in seriously ill animals with heart failure or impaired liver or kidney function.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not administer to horses in the last month of pregnancy.

6. SPECIAL WARNING(S)

For Animal Treatment Only

Special precautions for use in animals

The product should not be used in horses with pre-existing AV blocks, with severe cardiac insufficiency, respiratory disease or chronic renal failure.

Careful consideration should be given prior to administration to animals in shock and to animals with liver or kidney disease.

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.

Routine safety measures should be employed to protect practitioners and handlers

To the user:

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.

Immediately after exposure, wash the exposed skin 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 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.

Advice to the Doctor:
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.

Pregnancy and lactation:

Not to be used in mares in the last month of pregnancy.
No studies have been conducted in mares; however trace amounts of detomidine have been detected in the milk of cows treated with the product.

The safety of the product has not been investigated in breeding horses; use only according to benefit/risk assessment during the other months of pregnancy.

Interaction with other medicinal products and other forms of interaction:

Use 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 detomidine and ketamine has been used prior to maintenance with halothane. Because of the nature of the induction gents, the effects of halothane may be delayed and special care must be taken to avoid over-dosage.

When detomidine is used as a premedication prior to general anaesthesia, the product may delay onset of induction.

Use in conjunction with sympathomimetic amines and intravenous potentiated sulphonamides is contra-indicated.

Overdose:

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 µg/kg).

AV blocks may be prevented by IV administration of atropine at 0.005 - 0.02 mg/kg. Atropine raises the heart rate but may cause arrhythmias and should be used with caution.

Major incompatibilities:

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

7. ADVERSE EVENTS

Adverse reactions are very rare. 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 sinoatrial blocks), changes in the respiratory rate, incoordination/ataxia and sweating.

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

The potential for isolated cases of hypersensitivity exists, including paradoxical response (excitation).

Partial, transient penis prolapse may occur in male horses.

In rare cases, horses may show signs of mild colic following administration of alpha-2 adrenoceptor agonists because substances of this class inhibit intestinal motility.

Occasional reports of urticaria have been received. Mild adverse reactions have reportedly resolved without treatment. Severe reactions should be treated symptomatically.

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The product alone
To be administered intramuscularly or by slow intravenous injection at a concentration of 10-80 µg detomidine / kg bodyweight depending on the degree of sedation required.

Detomidine/butorphanol combination
Dosage: 0.1 ml product/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 5mg detomidine and 10 mg butorphanol affords effective, safe sedation in horses above 200 kg bodyweight.

Detomidine/ketamine combination (short duration anaesthesia)
Ketamine must not be used as the sole anaesthetic agent in horses. It is always necessary to administer detomidine prior to ketamine and to allow sufficient time (5 minutes) for sedation to develop. The two agents must therefore never be administered simultaneously in the same syringe. It is important that, to obtain satisfactory surgical anaesthesia the following procedure is followed: Administer the product at a dose rate of 20 µg/kg by slow intravenous injection.

Allow 5 minutes for the horse to become deeply sedated 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 and if for any reason it is necessary to prolong anaesthesia, thiopentone sodium can be administered intravenously in boluses of 1 mg/kg as required. Total doses of 5 mg/kg increments have been given. Total doses greater than this may reduce the quality of recovery.

Thiopentone can also be administered (as above regime) if sufficient depth of anaesthesia is not achieved.
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.

9. ADVICE ON CORRECT ADMINISTRATION

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 the product, then ketamine should not be injected and the anaesthesia procedure should be abandoned.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 1 Day
Milk: 12 hours

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Dispose of any unused veterinary medicinal product, or waste materials derived from such veterinary medicinal product, in accordance with local requirements.

These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V (‘To be supplied only on veterinary prescription’)

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Cardboard box with one glass vial.
Pack sizes:
5 ml (in a 10 ml sized vial)
10 ml
20 ml
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

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

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

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

United Kingdom (Great Britain)
Anupco Ltd.
Lodge House, Lodge Park,
Lodge Lane, Langham, Colchester, Essex, CO4 5NE

Tel: +44 (0) 1206 233528
Email sales@kela.health

17. OTHER INFORMATION

Approved 24 August 2023