ANNEX III LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Detogesic 10 mg/ml Solution for Injection for Horses
Detomidine hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
10 mg detomidine hydrochloride (equivalent to 8.36 mg detomidine)
1 mg methyl parahydroxybenzoate (E218) as a preservative

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml
15 ml

5. TARGET SPECIES

Horse.

6. INDICATION(S)

For the sedation and slight analgesia of horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use only. The product should be injected slowly. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 2 days; Milk: 12 hours.

9. SPECIAL WARNING(S), IF NECESSARY

Because of the limited space on cardboard box, we propose following text to be approved, which differs from the approved QRD text:

Read the package leaflet before use. User warnings are stated in the package leaflet.

User warnings

Care should be taken to avoid accidental self-injection. In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE as sedation and changes in blood pressure may occur. Wash splashes from skin and eyes. Pregnant women and women of child-bearing age should exercise caution when handling this product. Alpha-2-adrenoceptor agonists can cause severe adverse reactions. You must read the full user warnings on the package leaflet before using this product.

10. EXPIRY DATE

EXP:
Discard remaining contents 28 days after withdrawal of the first dose.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original carton in order to protect from light. Store in a dry place.

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

Disposal advice: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

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

Vetcare Limited, PO Box 99, 24101 Salo, Finland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 03379/4000

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

UNITS INJECTION VIAL (10 ml, 15 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Detogesic 10 mg/ml Solution for Injection for Horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Detomidine hydrochloride 10 mg/ml (detomidine 8.36 mg/ml)
Methyl parahydroxybenzoate 1 mg/ml

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

10 ml
15 ml

4. ROUTE(S) OF ADMINISTRATION

IV

5. WITHDRAWAL PERIOD

Withdrawal periods: Meat and offal, 2 days; Milk, 12 hours.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP
Once broached use by:…

8. THE WORDS ”FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Detogesic 10 mg/ml Solution for Injection for Horses

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

Marketing authorisation holder: Vetcare Limited, PO Box 99, 24101 Salo, Finland

Manufacturer for the batch release:
For product manufactured in Ireland only:
Ballinskelligs Veterinary Products, Co Kerry, Ireland

For product manufactured in Spain only:
Laboratorios SYVA s.a.u., Avda Párroco Pablo Díez 49-57, 24010 León, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Detogesic 10 mg/ml Solution for Injection for Horses
Detomidine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

A clear, almost colourless solution for intravenous injection.
1 ml contains 10 mg detomidine hydrochloride as active substance (8.36 mg detomidine) and
1mg methyl parahydroxybenzoate as preservative.

4. INDICATION(S)

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 pre-medication prior to administration of injection or inhalation anaesthetics.

See section 12. Special Warnings - ”Special precautions for use in animals” before use.

5. 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.

Please refer to section 12. Special warnings - ”Use in pregnancy and lactation” and ”Interactions with other medicinal products”.

6. ADVERSE REACTIONS

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)

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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Horse.

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

Administration route

For intravenous 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Meat and offal: 2 days; Milk: 12 hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C. Store in the original carton in order to protect from light. Store in a dry place.

Do not use after the expiry date which is stated on the carton after EXP.
Discard remaining contents 28 days after withdrawal of the first dose. 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 worked out. This discard date should be written in the space provided on the vial label.

12. SPECIAL WARNING(S)

For animal treatment only.

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.

User warnings

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 alpha2-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.

Use in pregnancy and lactation

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.

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 mcg /kg).

Interactions with other medicinal products

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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Legal category

Veterinary prescription only.

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.

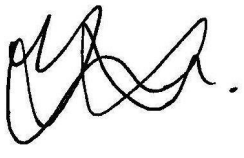
The vials are closed with pierceable rubber stoppers secured with aluminium crimps.

Not all pack sizes may be marketed.

Further information

The active ingredient in the product is 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-2adrenoceptors and observed analgesic effects are due to inhibition of transmission of the pain impulses within the CNS.

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



Approved: 26 September 2019