<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domidine 10 mg/ml, solution for injection for horses and cattle
Detomidine hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:
Active substances:
Detomidine hydrochloride 10.0 mg
this corresponds to 8.36 mg detomidine base
Excipients:
Methyl parahydroxybenzoate (E 218) 1.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5, 10, 20 ml

5. TARGET SPECIES

Horses and cattle

6. INDICATION(S) Not mandatory

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse, cattle
Meat and offal: 2 days.
Milk: 12 hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

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

disposal: read package leaflet
-----{national item}

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

For animal treatment only
Veterinary surgeon use only

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

{Number allocated by MS}

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domidine 10 mg/ml, solution for injection for horses and cattle
Detomidine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Compostion
1 ml solution for injection contains:
Active substance: Detomidine hydrochloride 10.0 mg

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

5 / 10 / 20 ml

4. ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular administration.

5. WITHDRAWAL PERIOD

Horse, cattle
Meat and offal: 2 days.
Milk: 12 hours.

6. BATCH NUMBER

Lot{number}

7. EXPIRY DATE

EXP {month/year}
Once opened,/broached use by ….

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Domidine 10 mg/ml, solution for injection for horses and cattle

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

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domidine 10 mg/ml, solution for injection for horses and cattle
Domidine vet. (Denmark)
Domodin vet. (Sweden, Finland)
Detomidine hydrochloride

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

1 ml solution for injection contains:
Active substances:
Detomidine hydrochloride 10.0 mg
this corresponds to 8.36 mg detomidine base

Excipients:

Methyl parahydroxybenzoate (E 218) 1.0 mg

Clear and colourless solution

4. INDICATION(S)

For the sedation and slight analgesia of horses and cattle, to facilitate physical examinations and treatments, such as minor surgical interventions.
Detomidine can be used for:

- Examinations (e.g. endoscopia, 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.

5. CONTRAINDICATIONS

Do not use in animals with cardiac abnormalities or respiratory diseases.
Do not use in animals with liver insufficiency or renal failure.
Do not use in animals with general health problems (e.g. diabetes mellitus, dehydrated animals, shock or any other extraordinary stress conditions).
Do not use in combination with butorphanol in horses suffering from colic.
See also 12. Use during pregnancy and lactation and interactions

6. ADVERSE REACTIONS

Injection of detomidine may cause the following side effects:

- Bradycardia
- Transient hypo- and/or hypertension.
- Respiratory depression, rarely hyperventilation,
- Increase in blood glucose
- As with other sedatives, in rare cases paradoxical reactions (excitation) can develop.
- Ataxia
- In horses: Cardiac arrhythmia, atrioventricular and sino-atrial block
- In cattle: Inhibition of rumen motility, tympania, paralysis of the tongue.

At doses above 40 µg/kg, the following symptoms can also be observed: sweating, pilo-erection and tremor of muscles, transient penis prolaps in stallions and geldings and mild, transient tympania of rumen and increased salivation in cattle.
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.
A diuretic effect is usually observed within 45 to 60 minutes after treatment.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse and cattle

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

For intravenous (IV) or intramuscular (IM) administration. The product should be injected slowly. Onset of effect is more rapid following intravenous administration.

Dosage in µg /kg	Dosage in ml/100 kg	Level of sedation	Commencement of effect (min)		Duration of effect (hrs)
			horse	cattle	
10-20	0.1-0.2	Light	3-5	5-8	0.5-1
20-40	0.2-0.4	Moderate	3-5	5-8	0.5-1

When prolonged sedation and analgesia is required, doses of 40 to 80 µg /kg bw can be used. The duration of effect is up to 3 hours.
For combination with other product to intensify the sedation or for premedication prior to general anaesthesia, doses of 10 to 30 µg /kg can be used.
It is recommended to wait 15 minutes after the detomidine administration before starting the planned procedure.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Horse, cattle
Meat and offal: 2 days.
Milk: 12 hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not use after the expiry date stated on the label after EXP
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 worked out. This discard date should be written in the space provided on the carton.
This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNING(S)

Special warnings for each target species
None

Special precautions for use in animals
As sedation begins, especially horses may start to sway and lower the head rapidly while they remain standing. Cattle and especially young cattle will try to lie down. To prevent injuries the location should therefore be chosen carefully. To avoid aspiration of feed or saliva, cattle should be maintained in upright position following treatment and head and neck of cattle lying down should be lowered. Especially for horses precautions should be taken to prevent self-injury. Detomidine should be prescribed with caution in horses which present with signs of colic or impaction.
Animals suffering from a shock or liver or kidney disease should only be treated according to the benefit risk assessment by the responsible veterinarian. Detomidine/butorphanol combination should not be used in horses with a history of liver disease or heart abnormalities.
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 sedation animals should remain in calm surroundings.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician 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 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 physician.

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 during pregnancy and lactation
Do not use this product during the last trimester of pregnancy. Use only according to the benefit/risk assessment of the responsible veterinarian during pregnancy.

Interactions with other medicinal products and other forms of interaction
Simultaneous use with other sedatives only after consultation of the warnings and precautions of the product concerned. Detomidine should not be used in combination with sympathomimetic amines such as adrenaline, dobutamine and ephedrine. The concurrent use of certain sulphonamides may cause heart arrhythmias with fatal outcome. Therefore do not use in combination with sulphonamides.
Detomidine in combination with other sedatives and anaesthetics should be used carefully because additive or synergistic effects may be possible. Where anaesthesia is started 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, the product may delay the onset of induction.

Incompatibilities
In the absence of incompatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products in the same syringe.

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

In the event of an accidental overdose, heart arrhythmias, hypotension, delayed recovery and profound central nervous system and respiratory depression may occur. Should the effects of detomidine become life-threatening, administration of an α_2-adrenergic antagonist is recommended.

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

Disposal advice
Medicines should not be disposed of via wastewater or household waste. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MM/JJJJ

15. OTHER INFORMATION
Pack sizes: 5, 10 or 20 ml.
Not all pack sizes may be marketed {National item}