Outer packaging (folding carton)

NAME OF THE VETERINARY MEDICINAL PRODUCT

Medesedan 10 mg/ml, Solution for Injection for Horses and Cattle

Detomidine hydrochloride

STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:

Active substance:

Detomidine hydrochloride 10.0 mg

(equivalent to 8.36 mg detomidine)

Excipient:

Methyl parahydroxybenzoate (E 218) 1.0 mg

PHARMACEUTICAL FORM

Solution for injection

PACKAGE SIZE

1 vial with 5 ml solution for injection.

5 vials with 5 ml solution for injection each one.

1 vial with 20 ml solution for injection.

5 vials with 20 ml solution for injection each one.

TARGET SPECIES

Horse and cattle.

INDICATION(S)

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

For premedication prior to administration of injection- or inhalation anaesthetics.

METHOD AND ROUTE(S) OF ADMINISTRATION

The product is intended for intramuscular or intravenous injection.

WITHDRAWAL PERIOD

Horse, cattle:

Meat and offal: 2 days

Milk: 12 hours

SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

EXPIRY DATE

EXP:

Shelf-life after first opening of the immediate packaging: 28 days.

Discharge any product remaining in the container at this time.

Once opened, use by…….

SPECIAL STORAGE CONDITIONS

Not applicable.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

For animal treatment only.

Keep out of the reach and sight of children.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

Ostlandring 13, 31303 Burgdorf, Germany

Tel: 0049 (0) 5136 6066 0; Tel: 0049 (0) 5136 6066 66; Email: info@cp-pharma.de

MARKETING AUTHORISATION NUMBER

Batch:

Immediate Packaging (glass vial)

NAME OF THE VETERINARY MEDICINAL PRODUCT

Medesedan 10 mg/ml, Solution for Injection for Horses and Cattle

Detomidine hydrochloride

QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml solution for injection contains:

Active substance:

Detomidine hydrochloride	10.0 mg
(equivalent to 8.36 mg detomidine)	

Excipient:

Methyl parahydroxybenzoate (E 218)	1.0 mg

CONTENTS BY VOLUME

5 ml solution for injection or

20 ml solution for injection.

ROUTE(S) OF ADMINISTRATION

For intramuscular or intravenous use.

WITHDRAWAL PERIOD

Horse, cattle:

Meat and offal:	2 days
Milk:	12 hours

Batch:

EXP:

Shelf-life after first opening of the immediate packaging: 28 days.

Once opened, use by……..

For animal treatment only.

Keep out of the reach and sight of children.

Package Leaflet

PACKAGE LEAFLET

Cepesedan 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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepesedan 10 mg/ml, Solution for Injection for Horses and Cattle, Detomidine hydrochloride

Medesedan 10 mg/ml, Solution for Injection for Horses and Cattle

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

Cepesedan is a clear and colourless solution for injection containing:

Active substance:

Detomidine hydrochloride	10.0 mg/ml
(equivalent to 8.36 mg detomidine)	

Excipient:

Methyl parahydroxybenzoate (E218)	1.0 mg/ml

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. endoscopy, 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 12. before use.

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. dehydrated animals).

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

Do not use in the last trimester of pregnancy.

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 (excitations) can develop.
- Ataxia
- Uterine contractions
- 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 bodyweight, 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. Detomidine 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.

7. TARGET SPECIES

Horse, cattle.

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

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

Dosage in mcg/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 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.

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 should not be mixed with other veterinary medicinal products in the same syringe.

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.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label and on the carton.
Shelf-life after first opening the container: 28 days.

Only UK: 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 label.

Discharge any product remaining in the container at this time.

12. SPECIAL WARNING(S)

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. Especially for horses usual precautionary measures should be taken to prevent self-injury. To avoid ruminal bloat and aspiration of feed or saliva, cattle should be mantained in sternal recumbency during and followig treatment and head and neck of recumbent cattle should be lowered.
Animals suffering from shock or liver or kidney disease should only be treated according to the benefit risk assessment by the responsible veterinarian. 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, shock or any other extraordinary stress

conditions. Detomidine/butorphanol combination should not be used in horses with a history of liver disease or cardiac irregularities.
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.
In case of sustained effect it is necessary to protect the animals from heat or cold.

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 leaflet or the label 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, lactation or lay

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

Interaction with other medicinal products and other forms of interaction

Concurrent use of 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 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, the product may delay the onset of induction.

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

In the event of an accidental overdose, cardiac arrhythmias, hypotension, delayed recovery and profound CNS and respiratory depression may occur. Should the effects of detomidine become life-threatening, general measures for circulatory and respiratory stabilisation and administration of an alpha2-adrenergic antagonist are recommended..

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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

Pack sizes:

1 x 1 glass vial with 5 ml.

5 x 1 glass vials with 5 ml.

1 x 1 glass vial with 20 ml.

5 x 1 glass vials with 20 ml.

Not all pack sizes may be marketed.

only IE: VPA 10810/003/001

VPA Veterinary Practitioner Only