PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL ON VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE

Detomidine hydrochloride 10 mg/ml

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

10 ml

4. ROUTES OF ADMINISTRATION

Intravenous and intramuscular use.

5. WITHDRAWAL PERIOD

Horses and cattle
Meat and offal: 2 days
Milk: 12 hours

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP: MM/YY
Once opened, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. THE WORDS "SEE PACKAGE LEAFLET FOR FULL INSTRUCTIONS INCLUDING USER WARNINGS"

See package leaflet for full instructions including user warnings.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARDBOARD CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Detomidine hydrochloride 10 mg/ml
Methyl parahydroxybenzoate (E 218) 1.0 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10-ml vial

5. TARGET SPECIES

Horses and cattle

6. INDICATIONS

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, radiographs).
- 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 the administration of injectable or inhalational anaesthesia.

7. METHOD AND ROUTES OF ADMINISTRATION

Intravenous and intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horses and cattle
Meat and offal: 2 days

Milk: 12 hours

9. SPECIAL WARNINGS, IF NECESSARY

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

10. EXPIRY DATE

EXP: end MM/YY
Shelf-life after first opening the immediate packaging: 28 days
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.
Do not refrigerate or freeze.

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

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

[UK-IE]
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

Vetpharma Animal Health, S.L
Les Corts, 23
08028 Barcelona
Spain
Distributed by:

Forte Healthcare Ltd
Cougar Lane

Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32509/4022

17. MANUFACTURER'S BATCH NUMBER

Batch

PACKAGE LEAFLET

SOMNIPRON 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

Marketing authorisation holder
Vetpharma Animal Health, S.L
Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for the batch release
CHEMICAL IBÉRICA PV, S.L.
Ctra. Burgos-Portugal, Km. 256,
Calzada de Don Diego, 37448
Salamanca

Distributed by
Forte Healthcare Ltd
Cougar Lane
Naul
Co. Dublin
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each ml of solution contains:

Active substance:
Detomidine .....8.36 mg
(as detomidine hydrochloride 10.00 mg)

Excipients:
Methyl parahydroxybenzoate (E 218).....1.0 mg

4. INDICATIONS

For the sedation and slight analgesia to 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, radiographs).
- 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 the administration of injectable or inhalational anaesthesia. See section “Special Warnings” 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 combination with butorphanol in horses suffering from colic.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
See also section “Special warnings”.

6. ADVERSE REACTIONS

Detomidine injection may cause the following side effects:
- Bradycardia.
- Transient hypotension and/or transient hypertension.
- Respiratory depression, rarely hyperventilation.
- Increased blood glucose.
- As with other sedatives, paradoxical reactions (excitations) may occur in rare cases.
- Ataxia.
- Uterine contractions.
- In horses: cardiac arrhythmia, atrioventricular and sino-atrial blocks.
- In cattle: ruminal atony, tympanism, paralysis of the tongue.

At doses above 40 µg of detomidine hydrochloride per kg bodyweight, the following symptoms may also be observed: sweating, piloerection, muscle tremors, transient prolapse of the penis in stallions and geldings, mild and transient ruminal tympanism as well as hypersalivation in cattle.

In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) 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

Horses and cattle.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Administration by intravenous (IV) or intramuscular (IM) route.
The product should be injected slowly.
The onset of the effect is faster after IV administration than through IM.

Dosage in µg/kg (Detomidine hydrochloride)	Dosage in ml of solution per 100 kg	Level of sedation	Onset of effect (min)		Duration of effect (hours)
			Horses	Cattle	
10-20	0.1-0.2	Mild	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 are required, doses of 40 to 80 µg of detomidine hydrochloride per kg bodyweight may be used. The duration of the effect can reach 3 hours. Doses of 10 to 30 µg of detomidine hydrochloride per kg may be used in association with other products to enhance sedation or in premedication prior to general anaesthesia. It is recommended to wait 15 minutes after the administration of detomidine before starting the therapeutic procedure.
The weight of the animal to be treated should be determined as precisely as possible to avoid overdose.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Horses and cattle
- Meat and offal: 2 days
- Milk: 12 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.
Do not refrigerate or freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after “EXP”. The expiry date refers to the last day of that month. Shelf-life after first opening the container: 28 days.

[ES, FR] Discard any product remaining in the container after 28 days of the first opening.

[UK-IE] When the container is broached/opened for the first time, using the in-use shelf-life, which is specified on this packager 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 WARNINGS

Special warnings for each target species
None.

Special precautions for use in animals
To avoid ruminal bloat and aspiration of feed or saliva, cattle should be maintained in sternal recumbency during and following treatment and the head and neck of recumbent cattle should be lowered”.
In cases of prolonged sedation it is necessary to monitor and help maintain the animal’s normal body temperature.
In horses especially, when sedation begins, animals can slip and lower the head while standing. On the other hand, cattle, especially young cattle, tend to lie down. Therefore, it is necessary to carefully choose the location for treatment to prevent injuries. Moreover, the usual precautionary measures must be taken, particularly when the product has to be administered to horses, to prevent human or animal injury.
Animals in shock or with kidney or liver disease should only be treated after the benefit/risk assessment made by the responsible veterinarian.
It is not recommended to use this product in animals with heart disease (with pre-existing bradycardia or risk of atrioventricular block), respiratory or hepatic or renal failure, shock or under extraordinary stress conditions.
It is not recommended to use the combination detomidine/butorphanol in horses with a history of liver disease or cardiac arrhythmia. Detomidine should be prescribed with caution in horses which present with signs of colic or impaction.
It is not recommended to feed the animals for 12 hours before anaesthesia nor to give water or feed before the drug effect has passed.
In the case of painful procedures, detomidine should be used in combination with an analgesic or local anaesthetics.
While waiting for the sedative to take effect, it is recommended to keep the animals in a quiet environment.

User warnings
In the case of accidental oral intake or self-injection seek medical advice immediately and show the package leaflet to the doctor.

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 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.

Use during pregnancy, lactation or lay

Do not use 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

Concomitant use with other sedatives should only be done after the consultation of contraindications and precautions of use of these products.
Detomidine should not be used in conjunction with sympathomimetic amines such as adrenaline, dobutamine and ephedrine except as required in anaesthetic emergencies.
Concomitant use with certain potentiated sulphonamides may cause fatal cardiac arrhythmia. Do not use in conjunction with sulphonamides.
Concomitant use of detomidine with other sedatives and anaesthetics requires caution because additive/synergistic effects are possible.
When induction of anaesthesia with detomidine and ketamine has been used prior to maintenance with halothane, the effects of halothane may be delayed. Therefore, special care must be taken to avoid overdose.
When detomidine is used as a premedication prior to general anaesthesia, detomidine may delay onset of induction

Overdose (symptoms, emergency procedures, antidotes)

Accidental overdose may cause cardiac arrhythmia, hypotension, delayed recovery, deep depression of the central nervous system and the respiratory system.
In cases of overdose, or should the effects of detomidine become life-threatening, general measures for circulatory and respiratory stabilisation and administration of an alpha-2 adrenergic antagonist is recommended.

Incompatibilities

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

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

Box with 1 vial of 10ml.

Approved 29 March 2018