SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOMNIPRON 10 mg/ml Solution for injection for horses and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear and colourless solution

4. CLINICAL PARTICULARS

4.1. Target species

Horses and cattle

4.2. Indications for use, specifying the target species

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. See section 4.5 before use.

4.3. 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 sections 4.7 and 4.8.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

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.

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 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.

4.6. Adverse reactions (frequency and seriousness)

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.

Due to the temporary inhibition of intestinal motility common to alpha-2 sympathomimetics, in very rare cases, horses may show symptoms of colic following the administration of the product. 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.

4.7. 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.

4.8. 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.

4.9. Amounts to be administered and administration route

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.

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

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.

4.11. Withdrawal periods

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: sedative and analgesic
ATC-vet code: QN05CM90

5.1. Pharmacodynamic properties

Detomidine is a sedative with analgesic properties (alpha-2 adrenergic agonist). The duration and intensity of the effect are dose-dependent. The mode of action of detomidine is based on the specific stimulation of the alpha-2 adrenergic central receptors. The analgesic effect is based on the inhibition of the transfer of pain impulses in the central nervous system.
Detomidine also acts on peripheral alpha receptors, which may cause an increase in blood glucose as well as piloerection. At higher doses, sweating and increased diuresis may occur. Blood pressure decreases initially and then returns to normal or slightly below normal values. Heart rate decreases. On ECG examination, there is a lengthening of the PR interval and in the horse a slight atrioventricular block is observed. These effects are transient. In most animals, a decrease in the respiratory rate is observed. Hyperventilation is observed in rare cases.

5.2. Pharmacokinetic particulars

Detomidine is rapidly absorbed after intramuscular injection. T_{max} is from 15 to 30 minutes. After intramuscular injection, bioavailability is 66 to 85%. The rapid distribution to tissues is followed by almost complete metabolism, mainly in the liver. The $t_{½}$ is 1 to 2 hours. The metabolites are mainly excreted in urine and faeces.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Methyl parahydroxybenzoate (E 218)
Sodium chloride
Water for injections

6.2. Incompatibilities

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

6.3. Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

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

6.5. Nature and composition of immediate packaging

Pack size: 10 ml
Type I clear glass vials which are fitted with a bromobutyl rubber stopper sealed with aluminium caps with plastic flip-off.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 32509/4022

9. DATE OF FIRST AUTHORISATION

23 March 2016

10. DATE OF REVISION OF THE TEXT

March 2018

Approved 29 March 2018