B. PACKAGE LEAFLET

PACKAGE LEAFLET:

SEDAQUICK 10 mg/ml solution for injection for horses and cattle (ES, IT, PT)

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

Marketing authorisation holder:
FATRO S.p.A.
Via Emilia, 285
40064, Ozzano dell'Emilia (BO)
Italy

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

Distributed by:
To be completed nationally.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEDAQUICK 10 mg/ml solution for injection for horses and cattle (ES, IT, PT)
Detomidine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Detomidine ..... 8.36 mg
(equivalent to detomidine hydrochloride 10.0 mg)

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

Clear and colourless solution.

4. INDICATION(S)

A sedative with analgesic properties used to facilitate handling of horses and cattle for examination, minor surgical interventions and other manipulations.

The product is also indicated for use prior to the administration of injectable or gaseous anaesthetics to carry out surgical procedures of short duration.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in seriously ill animals with respiratory disease, heart failure or impaired hepatic or renal function.
Do not use in animals with general health problems (for example in dehydrated animals).
Do not use in combination with butorphanol in horses suffering from colic.
See sections “Adverse reactions” and “Special warnings”.

6. ADVERSE REACTIONS

In rare cases, the following side effects have been reported:
- Paradoxical reactions (excitations), as with other sedatives.
- In horses: cardiac arrhythmia, atrioventricular and sino-atrial blocks.

In very rare cases, the following side effects have been reported:
- Bradycardia.
- Transient hypotension and/or transient hypertension.
- Respiratory depression, rarely hyperventilation.
- Increased blood glucose.
- Ataxia.
- Urticaria
- Uterine contractions.
- Sweating, piloerection, muscle tremors
- Transient prolapse of the penis in stallions and geldings.
- A diuretic effect is usually observed within 45 to 60 minutes after treatment.
- Horses may show symptoms of colic following the administration of the product, due to the temporary inhibition of intestinal motility common to α2-sympathomimetics. Detomidine should be prescribed with caution in horses with colic or indigestion signs.
- In cattle: ruminal atony, tympanism, paralysis of the tongue as well as hypersalivation.

Mild adverse reactions have been reported that resolve without treatment. Severe adverse reactions should be treated symptomatically.

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.

7. TARGET SPECIES

Horses and cattle.

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

Intravenous and intramuscular use.

The product should be injected slowly.
The onset of the effect is faster after IV administration than through IM.
Dose: 10 – 80 µg detomidine/kg bw. depending on the degree of sedation required:

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.

9. ADVICE ON CORRECT ADMINISTRATION

The weight of the animal to be treated should be determined as precisely as possible to avoid overdose.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

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.
The use of the product in animals in shock or animals with heart or respiratory disease as well as animals with renal or hepatic disease should only be made after a benefit/risk evaluation by the responsible veterinarian.It is not recommended to use the combination detomidine/butorphanol in horses with a history of liver disease or cardiac arrhythmia.
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 ingestion or self-injection 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.
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 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.

To the physician:
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.

Pregnancy and lactation:
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:
Where appropriate the product may be used in conjunction with local anaesthetic agents.
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.
If recovery is delayed, it should be ensured that the animal recover in a quiet and warm place. An oxygen supplement may be indicated in case of circulatory and respiratory depression.
In cases of overdose, or should the effects of detomidine become life-threatening, general measures for circulatory and respiratory stabilization and administration of an alpha2-adrenergic antagonist (atipamezole) is recommended (dose 2-10 higher than the dose of detomidine).

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal 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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Package size:
Box with 1 vial of 10 ml.

(For Spain only, include:
For animal treatment only – to be supplied only on veterinary prescription.
Administration only by a veterinary surgeon.)