SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEDAQUICK 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
(equivalent to 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

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.

4.3. Contraindications

Do not use in case 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 poor general health (for example in dehydrated animals).
Do not use in combination with butorphanol in horses suffering from colic.
See sections 4.6, 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.
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.

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.
- Urticaria
- Uterine contractions
- Sweating, piloerection, muscle tremors
- A diuretic effect is usually observed within 45 to 60 minutes after treatment.

- In cattle: ruminal atony, tympanism, paralysis of the tongue as well as hypersalivation.

- In horses: cardiac arrhythmia, atrioventricular and sino-atrial blocks. Transient prolapse of the penis in stallions and geldings.

Due to the temporary inhibition of intestinal motility common to α2-sympathomimetics, in very rare cases, horses may show symptoms of colic following the administration of the product. Detomidine should be prescribed with caution in horses with colic or indigestion signs.

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 displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7. Use during pregnancy, lactation or lay

The use is not recommended during the last trimester of pregnancy.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian for the other pregnancy months.

4.8. 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.

4.9. Amounts to be administered and administration route

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 b.w. (Detomidine hydrochloride)	Injection volume ml/100kg b.w.	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)

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).

4.11. Withdrawal period

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Hypnotics and sedatives
ATC-vet code: QN05CM90

5.1. Pharmacodynamic properties

Detomidine is a sedative with analgesic properties (α2-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 α2-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 α 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. Tmax 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 t½ 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 veterinary medicinal 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.

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

FATRO S.p.A.
Via Emilia, 285
40064, Ozzano Emilia (BO)
Italy

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT