1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedecalm 1 mg/ml solution for injection for dogs and cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Medetomidine hydrochloride..... 1 mg

(equivalent to 0.85 mg of medetomidine)

Excipients:

Methyl parahydroxybenzoate (E218)..... 1.0 mg

Propyl parahydroxybenzoate (E216)..... 0.2 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

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs and cats:
- Sedation in order to facilitate the restraint of animals during clinical examinations.
- Premedication prior to general anaesthesia.

4.3 Contraindications

Do not use in animals with serious cardiovascular disease, respiratory disease or hepatic or renal disorders.
Do not use in cases of obstructive disorders of the gastrointestinal tract (such as torsion of the stomach, blockage, obstruction of the oesophagus).
Do not use in cases of known hypersensitivity to the active substance or any excipients.
Do not use in animals with diabetes mellitus.
Do not use in animals in a state of shock, emaciation or serious debilitation.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.
Do not administer concomitantly with sympathomimetics or sulphonamides and trimethoprim.
See Section 4.7.

4.4 Special warnings for each target species

Medetomidine may not provide analgesia throughout the entire sedation period; therefore, the use of additional analgesics should be considered during painful surgical procedures.

4.5 Special precautions for use

i) Special precautions for use in animals

Medetomidine can produce respiratory depression; in such cases, manual ventilation and administration of oxygen may be required.
A clinical examination should be carried out in all animals before the use of veterinary medicinal products for sedation and/or general anaesthesia. When the product is used for premedication, the dose of the anaesthetic should be reduced accordingly and titrated to response, due to the considerable variability in requirements between patients. Before using any combinations, the warnings and contraindications in the product literature for the other product(s) should be observed.
Higher doses of medetomidine should be avoided in large breed dogs. Care should be taken when combining medetomidine with other anaesthetics or sedatives because of its marked anaesthetic sparing effects.
Animals should be fasted 12 hours before anaesthesia.
The animal should be placed in calm and quiet surroundings to let the sedation gain its maximum effect. This takes about 10-15 minutes. Do not start any procedure or give other medicines before maximum sedation is reached.
Treated animals should be kept warm and at a constant temperature, both during the procedure and during recovery.
The eyes should be protected by a suitable lubricant.

Animals should be allowed to calm down before initiation of treatment.
Sick and debilitated dogs and cats should only be premedicated with medetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.
Care should be taken with use of medetomidine in animals with cardiovascular disease, or which are old or in general poor health. Liver and kidney function should be evaluated prior to use.
In order to reduce the recovery time after anaesthesia or sedation, the effect of the product can be reversed by the administration of an alpha-2-antagonist such as atipemazole. Atipamezole does not reverse the effect of ketamine. As ketamine alone can elicit convulsions in dogs and cramps in cats, alpha-2 antagonists should not be given less than 30 - 40 min. after the administration of ketamine.

ii) 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 insert or label to the physician. 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 case of accidental contact of the product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.
Special precautions should be taken in pregnant women handling the product, to avoid self-injection. Uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.
Advice to physicians:
Medetomidine 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)

Very rarely, cardiovascular effects such as bradycardia with atrioventricular block (1st and 2nd degree) and occasionally, extrasystoles, vasoconstriction of coronary artery, decreased cardiac output and increase of blood pressure just after the administration of product (followed by a return to the normal value or slightly below), can occur.
Some dogs and most cats will vomit 5 - 10 minutes after injection. Cats may also vomit on recovery.
Pulmonary oedema, respiratory depression and cyanosis, increase of diuresis, hypothermia, sensitivity to loud noises, reversible hyperglycaemia due to a

depression of insulin secretion, pain at the injection site and muscle tremors, can also occur.
In cases of cardiovascular and respiratory depression, assisted ventilation and administration of oxygen may be indicated. Atropine can increase the cardiac rate.
Dogs weighing less than 10 kg can present frequently with the above-mentioned adverse reactions.
Incidents of prolonged sedation and recurrence of sedation after initial recovery have been reported.
The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- Common (more than 1 but less than10 animals in 100 animals)
- Uncommon (more than one 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 safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore, do not use the drug during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

The concomitant administration of other central nervous system depressants should be expected to potentiate the effect of either product and appropriate dose adjustment should be made.
Medetomidine has marked anaesthetic sparing effects (see section 4.5 of the SPC).
The effects of medetomidine can be antagonised by the administration of atipamezole.

Bradycardia may be partially prevented by prior administration (at least 5 minutes before) of an anticholinergic agent; however the administration of anticholinergic agents to treat bradycardia either simultaneously with medetomidine, or following sedation with medetomidine, could lead to adverse cardiovascular effects.

4.9 Amounts to be administered and administration route

Dogs: Intramuscular or intravenous injection
Cats: Intramuscular, intravenous or subcutaneous injection

Dogs:

For sedation, the product should be administered at the rate of 10 - 80 µg of medetomidine hydrochloride per kg of body weight by the intravenous or the intramuscular route.
Maximal effect is obtained within 15 - 20 minutes. Clinical effect is dose-dependent, lasting 30 to 180 minutes.

For premedication, the product should be administered at a dose of 10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1 - 0.4 ml per 10 kg body weight. The exact dose depends on the combination of drugs used and the dosage(s) of the other drug(s).
The dose should furthermore be adjusted to the type of surgery, length of procedure and patient temperament and weight. Premedication with medetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. Before using any combinations, product literature for the other products should be observed. See also section 4.5.

Cats:
For sedation, the product should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride per kg body weight (corresponding to 0.05 – 0.15 ml/ kg body weight).

For premedication for anaesthesia, the product should be administered at a dosage of 80 µg medetomidine hydrochloride per kg body weight (corresponding to 0.08 ml/ kg body weight).

The speed of induction is slower when subcutaneous route of administration is used.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

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

In cases of overdosage, the principal signs are prolonged anaesthesia or sedation. In some cases, cardiorespiratory effects may occur. The treatment consists of the administration of an alpha-2 antagonist, such as atipamezole, provided that reversal of sedation is not dangerous for the animal (atipamezole does not reverse the effects of ketamine, which used alone can produce convulsions in dogs and cramps in cats). Alpha-2-antagonists should not be given less than 30 - 40 minutes after the administration of ketamine.
Atipamezole hydrochloride is administered by the intramuscular route at the following dosages: 5 times the initial dose of medetomidine hydrochloride

administered to dogs (µg/kg) and 2.5 times for cats. The volume of atipamezole hydrochloride 5 mg/ml is equal to the volume of medetomidine hydrochloride administered in the case of dogs; for cats, the volume of the antagonist should be half that of medetomidine hydrochloride administered.
If it is imperative to reverse bradycardia but to maintain sedation, atropine may be used.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Hypnotics and sedatives
ATC vet code: QN05CM91.

5.1 Pharmacodynamic properties

Medetomidine is a sedative agent which presents analgesic and myorelaxant properties. It is a selective agonist specific for, and binding with high affinity to, the alpha-2-adrenergics receptors. The activation of these receptors induces a decrease in the release and turnover of noradrenaline in the central nervous system which manifests as sedation, analgesia and bradycardia. At the peripheral level, medetomidine causes vasoconstriction by stimulation of post-synaptic alpha-2-adrenergic receptors, which produce a transitory hypertension. Blood pressure returns to normal levels, even to a moderate hypotension within 1 to 2 hours. Respiratory rate can be reduced temporarily.
The time and depth of sedation and analgesia are dose dependent. When the effect is maximal, the animal is relaxed and does not respond to external stimulation. Medetomidine acts in a synergic manner with ketamine or opiates, such as fentanyl, resulting in a better anaesthesia. The necessary amount of volatile anaesthesics (e.g. halothane) is reduced by medetomidine. In addition to its sedative, analgesia and myorelaxant properties, medetomidine also exerts hypothermic and mydriatic effects, inhibits salivation and decreases intestinal motility.

5.2 Pharmacokinetic particulars

After intramuscular injection, medetomidine is rapidly and almost completely absorbed at the site of injection and its pharmacokinetics are very similar to that observed after intravenous injection. Maximum plasma concentrations are reached within 15 to 20 minutes. Estimated plasma half-life is 1.2 hours for dogs and 1.5 hours for cats. Medetomidine is mainly oxidised in the liver, while a small amount is methylated in the kidney. Metabolites are primarily excreted in urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Sodium chloride
Water for injections

6.2 Major 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type I clear glass vials of 10 ml capacity. Vials are fitted with a bromobutyl stopper and sealed with an aluminium cap.
Pack sizes:
- Box with 1 vial
- Box with 5 vials
- Box with 6 vials

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Industrial Veterinaria, S.A.

Esmeralda 19
E-08950 Espluges de Llobregat
E-08950 Espluges de Llobregat
Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10509/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th February 2016

10 DATE OF REVISION OF THE TEXT

March 2018