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…….. 1.0 mg

(equivalent to 0.85 mg of medetomidine)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.0 mg
Propyl parahydroxybenzoate	0.2 mg
Sodium chloride	
Water for injections	

Clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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

3.3 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 hypersensitivity to the active substance or to any of the 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 use concomitantly with sympathomimetics or sulphonamides and trimethoprim.
See Section 3.7.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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.

Medetomidine can produce respiratory depression; in such cases, manual ventilation and administration of oxygen may be required.

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 a calm and quiet environment to reach a maximum sedative effect. This takes about 10-15 minutes. Do not start any procedure or administer 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. Vomiting and perianesthetic reflux may occasionally lead to regurgitation of gastric contents to the mouth.

Due to decreased tear flow, the eyes should be protected by a suitable lubricant (appropriate ophthalmic ointment or artificial tear solution).

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 veterinary medicinal product can be reversed by the administration of an alpha-2-antagonist such as atipamezole.

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. It should be considered that bradycardia might persist after reversal.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product is a sedative. Care should be taken to avoid skin, eye, mucosal contact and self-injection.
In the case of accidental contact of the veterinary medicinal product with the skin or eyes, rinse with large amounts of fresh water. Remove contaminated clothes that are in direct contact with skin. If symptoms occur, seek medical advice.
In 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.

Pregnant women should handle the veterinary medicinal product with special care 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia, Heart block 1st degree, Heart block 2nd degree, Extrasystole, Hypertension[1], Hypotension[1], Decreased cardiac output, Coronary artery disorder[2], Cardiac depression[3] Vomiting[4] Pulmonary oedema, Respiratory depression[3] Cyanosis, Hypothermia Polyuria Increased sensitivity to sound, Muscle tremor, Sedation prolonged, Recovery prolonged[5] Hyperglycaemia[6] Injection site pain

[1] Blood pressure will increase initially after administration and then return to normal, or slightly below normal.
[2] Vasoconstriction of coronary artery.
[3] Manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate.
[4] Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery.
[5] Recurrence of sedation after initial recovery has been reported.
[6] Reversible hyperglycaemia due to depression of insulin secretion.

Dogs with a body weight of less than 10 kg may show the undesirable effects mentioned above more often.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.

3.8 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 3.5 of the SPC).
The dose of compounds such as propofol and volatile anaesthetics should be reduced accordingly.
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.

3.9 Administration routes and dosage

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

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

Dogs:
For sedation:
The veterinary medicinal product should be administered at a dose of 10-80 µg of medetomidine hydrochloride per kg of body weight (corresponding to 0.1 – 0.8 ml/ 10 kg body weight).
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting 30 to 180 minutes.

For premedication:
The veterinary medicinal product should be administered at a dose of 10-40 µg medetomidine hydrochloride per kg body weight (corresponding to 0.1-0.4 ml/ 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 3.5.

Cats:
For sedation:
The veterinary medicinal product should be administered at a dose 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 veterinary medicinal product should be administered at a dose of 80 µg medetomidine hydrochloride per kg body weight (corresponding to 0.08 ml/ kg body weight).

Use the table below to determine the correct dosage on the basis of body weight.

	Dogs		Cats	
Body weight (kg)	**Sedation (ml)**	**Premedication (ml)**	**Sedation (ml)**	**Premedication (ml)**
1	0.01-0.08	0.01-0.04	0.05-0.15	0.08
2	0.02-0.16	0.02-0.08	0.10-0.30	0.16
3	0.03-0.24	0.03-0.12	0.15-0.45	0.24
4	0.04-0.32	0.04-0.16	0.20-0.60	0.32
5	0.05-0.40	0.05-0.20	0.25-0.75	0.40
6	0.06-0.48	0.06-0.24	0.30-0.90	0.48
7	0.07-0.56	0.07-0.28	0.35-1.05	0.56
8	0.08-0.64	0.08-0.32	0.40-1.20	0.64
9	0.09-0.72	0.09-0.36	0.45-1.35	0.72
10	0.10-0.80	0.10-0.40	0.50-1.50	0.80
12	0.12-0.96	0.12-0.48		
14	0.14-1.12	0.14-0.56		
16	0.16-1.28	0.16-0.64		
18	0.18-1.44	0.18-0.72		
20	0.20-1.60	0.20-0.80		
25	0.25-2.00	0.25-1.00		
30	0.30-2.40	0.30-1.20		
40	0.40-3.20	0.40-1.60		
50	0.50-4.00	0.50-2.00		

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

The stopper may be safely punctured up to 50 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.
Cardiovascular and/or respiratory impairment should be treated symptomatically providing the capability of assisted ventilation.
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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QN05CM91.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I clear glass vials. Vials are fitted with a bromobutyl stopper and sealed with an aluminium cap.

Package sizes:
- Carton box with 1 vial of 10 ml
- Carton box with 5 vials of 10 ml
- Carton box with 6 vials of 10 ml

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10509/007/001

8. DATE OF FIRST AUTHORISATION

05/02/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/07/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).