SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sededorm 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 medetomidine	0.85 mg)

Excipients:

Methyl parahydroxybenzoate (E218)	1.0 mg
Propyl parahydroxybenzoate	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

In 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 case of mechanical disorders of gastrointestinal tract (torsion of the stomach, imprisonment, obstruction of the oesophagus).
Do not administer in conjunction with sympathomimetic amines.
Do not use in case of known hypersensitivity to the active substance or to any of the excipients.

Do not use in animals with diabetes mellitus.
Do not use in animals with state of shock, emaciation or serious debilitation.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.
See Section 4.7.

4.4. Special warnings for each target species

It is possible that medetomidine does not provide analgesia throughout the entire sedation period. The use of additional analgesics should be considered during painful surgical procedures.

4.5. Special precautions for use

Special precautions for use in animals

During its use in premedication, the dosage of anaesthetic will be reduced in proportion and established according to the reaction of the animal, depending on the variability of response between animals. Special warnings and contraindications included in the literature of the other products should be respected before carrying out any association.

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

A clinical examination should be carried out in all animals before the use of veterinary medicinal products for sedation and/or general anaesthesia.

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 surrounding to let the sedation gain its maximum effect. This takes about 10-15 minutes. One should 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 recovery.

The eyes should be protected by a suitable lubricant.

Nervous, aggressive or excited animals should be given the possibility 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 elderly or in general poor health. Liver and kidney function should be evaluated prior to use.

In order to reduce the recovery time after anæsthesia or sedation, the effect of medetomidine 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 cramps, alpha-2 antagonists should not be given less than 30-40 min. after the administration of ketamine.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician but 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 the case of accidental contact of the product with eyes, rinse abundantly with 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.

Advice to doctors:
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)

The following adverse reactions may occur:

- Cardiovascular effects: bradycardia with atrioventricular block (1st and 2nd degree) and occasional extrasystoles, vasoconstriction of coronary artery, decreased cardiac output.
- Increase of blood pressure just after the administration of product and then return to the normal value or slightly below.
- Some dogs and most cats vomit 5 -10 minutes after injection. Cats may also vomit on recovery.

- Sensitivity to loud noises has been observed in some animals.
- An increase of diuresis, hypothermia, respiratory depression, cyanosis, a pain at the injection site and muscle tremors may also occur.

The following may also be observed:
- Cases of reversible hyperglycaemia due to a depression of insulin secretion.
- Cases of pulmonary oedema.

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.

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.

Do not administer concomitantly with sympathomimetics or sulfamides and trimethoprim.

4.9. Amounts to be administered and administration route

Dogs: intramuscular or intravenous injection

<u>For sedation</u>:
For sedation the product should be administered at the rate of 15-80 µg of medetomidine hydrochloride per kg of body weight I.V., or 20-100 µg of medetomidine hydrochloride per kg of body weight I.M.
Use the table below to determine the correct dosage on the basis of body weight.
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting 30 to 180 minutes.

Sededorm dosages in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw:

body weight [kg]	i.v.- Injection [ml]	corresp. to [µg/kg bw]	i.m.- Injection [ml]	corresp. to [µg/kg bw]
1	0.08	80.0	0.10	100.0
2	0.12	60.0	0.16	80.0
3	0.16	53.3	0.21	70.0
4	0.19	47.5	0.25	62.5
5	0.22	44.0	0.30	60.0
6	0.25	41.7	0.33	55.0
7	0.28	40.0	0.37	52.9
8	0.30	37.5	0.40	50.0
9	0.33	36.7	0.44	48.9
10	0.35	35.0	0.47	47.0
12	0.40	33.3	0.53	44.2
14	0.44	31.4	0.59	42.1
16	0.48	30.0	0.64	40.0
18	0.52	28.9	0.69	38.3
20	0.56	28.0	0.74	37.0
25	0.65	26.0	0.86	34.4
30	0.73	24.3	0.98	32.7
35	0.81	23.1	1.08	30.9
40	0.89	22.2	1.18	29.5
50	1.03	20.6	1.37	27.4
60	1.16	19.3	1.55	25.8
70	1.29	18.4	1.72	24.6
80	1.41	17.6	1.88	23.5
90	1.52	16.9	2.03	22.6
100	1.63	16.3	2.18	21.8

For premedication:
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: intramuscular injection, intravenous injection and subcutaneous

injection

For moderate-deep sedation and restraint of cats the product should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride /kg bw (corresp. to 0.05 – 0.15 ml/ kg bw). The speed of induction is slower when subcutaneous route of administration is used.

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, 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 intramuscular route at the following dosage: 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 volume of drug administered to dogs; for cats half of this volume should be used.

If it is imperative to reverse bradycardia but to maintain sedation, atropine may be used.

4.11. Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: sedative and analgesic.
ATC vet Code: QN05CM91.

5.1. Pharmacodynamic properties

Medetomidine is a sedative component which presents analgesic and myorelaxant properties. It is a selective agonist, specific and particularly effective for alpha-2-adrenergics receptors. The activation of these receptors induces a decrease in the release and turnover of noradrenalin in central nervous system which is declared by means of sedation, analgesia and bradycardia. At 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 maximum, 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 the salivation and decreases intestinal motility.

5.2. Pharmacokinetic particulars

After intramuscular injection, medetomidine is rapidly and almost completely absorbed in the site of injection and pharmacokinetics is 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.
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: 3 years.
Shelf-life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

Do not refrigerate or freeze.
Protect from light.
Protect from frost.

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. Vials are packed in a cardboard box.
Pack sizes:
- Box with 1 vial

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 product 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

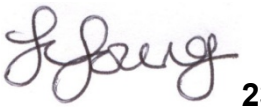
Vm 32509/4000

9. Date of first authorisation

31 March 2009

10. Date of revision of the text

December 2013

Approved:  **23/12/2013**