

Sedastart 1mg/ml Solution for Injection for Cats and Dogs

Introduction



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Presentation

A clear colourless, sterile aqueous solution for injection containing:

Active substance:

Medetomidine hydrochloride 1.0mg/ml (equivalent to 0.85mg/ml medetomidine)

Excipients:

Methyl parahydroxybenzoate(E218)1.0mg/ml

Propyl parahydroxybenzoate(E216)0.2mg/ml

Uses

In dogs and cats:

Sedation to facilitate handling. Premedication prior to general anaesthesia.

In cats: In combination with ketamine for general anaesthesia for minor surgical procedures of short duration.

Dosage and administration

Dogs

Intramuscular or intravenous injection.

Cats

Intramuscular injection.

Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dogs

For sedation Sedastart should be administered at the rate of 750µg medetomidine hydrochloride i.v. or 1000µg medetomidine hydrochloride i.m. per square metre of body surface. Use the table below to determine the correct dosage on the basis of body weight.

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

Body weight (kg)	i.v. Injection (ml)	Corresponding to (µg/kg bw)	i.m. Injection (ml)	Corresponding 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

Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting from 30-180 minutes.

For premedication, Sedastart should be administered at a dosage of 10-40µg medetomidine hydrochloride per kg body weight, corresponding to 0.1 – 0.4ml Sedastart per 10kg 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 special warnings section.

Cats

For moderate-deep sedation and restraint of cats Sedastart should be administered at a dosage of 50 – 150µg medetomidine hydrochloride / kg bw (corresp. to 0.05 – 0.15ml Sedastart / kg bw).

For anaesthesia Sedastart should be administered at a dosage of 80µg medetomidine hydrochloride / kg bw (corresp. to 0.08ml Sedastart / kg bw) and 2.5 to 7.5mg ketamine / kg bw. Using this dosage anaesthesia occurs within 3 – 4 minutes and is apparent for 20 – 50 minutes. For longer lasting procedures administration has to be repeated by using ½ of the initial dose (i.e. 40µg medetomidine hydrochloride (corresp. to 0.04ml Sedastart / kg bw) and 2.5 – 3.75mg ketamine / kg bw) or 3.0mg ketamine / kg bw alone. Alternatively, for longer lasting procedures anaesthesia may be extended by use of the inhalation agents isoflurane or halothane, with oxygen or oxygen/nitrous oxide.

Contra-indications, warnings, etc

Do not use in animals with: severe cardiovascular disease or respiratory diseases or impaired liver or kidney function; mechanical disturbances of the gastrointestinal tract (torsio ventriculi, incarcerations, oesophagal obstructions); pregnancy; diabetes mellitus; state of shock, emaciation or serious debilitation.

Do not use concomitantly with sympathomimetic amines. Do not use in cases of known hypersensitivity to the active substance or to any other excipients. Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

Adverse reactions

Bradycardia with atrioventricular block (1st and 2nd degree) and occasionally extrasystolia. Vasoconstriction of coronary artery. Decreased cardiac output. Blood pressure will increase initially after administration and then return to normal, or slightly below normal. Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery. Sensitivity to loud noises is observed in some individuals. Increased diuresis, hypothermia, respiratory depression, cyanosis, pain at injection site and muscle tremor may be seen. In individual cases reversible hyperglycaemia due to depression of insulin secretion. In circulatory and respiratory depression manual ventilation and oxygen supplement may be indicated. Atropine may increase the cardiac rate. Dogs with a body weight of less than 10kg may show the undesirable effects mentioned above more often.

Special warnings

Medetomidine may not provide analgesia throughout the entire period of sedation, therefore consideration should be given to providing additional analgesia for painful procedures.

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. The dose of the anaesthetic should be reduced accordingly and titrated to response due to considerable variability in requirements between patients. Before using any combinations, the warnings and contra-indications in the product literature for the other products should be observed.

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. As ketamine alone can elicit cramps, alpha-2 antagonists should be administered not before 30-40 min. after ketamine. Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered.

The concomitant administration of other central nervous system depressants should be expected to potentiate the effect of either active substance. Appropriate dose adjustment should be made. Medetomidine has marked anaesthetic sparing effects. The effects of medetomidine may be antagonized by administration of atipamezole or yohimbine.

The safety of the product has not been established during pregnancy and lactation. Therefore it should not be used during pregnancy and lactation.

Overdose

In the case of overdose the main signs are prolonged anaesthesia or sedation. In some cases cardio-respiratory effects may occur. For treatment of these cardio-respiratory effects of an overdose it is recommended to administer an alpha-2 antagonist e.g. atipamezole or yohimbine, provided that reversal of sedation is not dangerous to the patient (atipamezole does not reverse the effects of ketamine which may cause seizures in dogs and elicit cramps in cats when used alone). Use atipamezole hydrochloride 5 mg/ml intramuscularly in the dog in the same volume as Sedastart, in the cat use half the volume. The required dose of atipamezole hydrochloride corresponds in dogs to the 5-fold dose of the medetomidine hydrochloride dose in mg administered before and in cats to the 2.5-fold dose. Alpha-2 antagonists should be administered not before 30-40 min. after ketamine. If it is imperative to reverse bradycardia but maintain sedation, atropine may be used.

User warnings

In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert 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.

Pharmaceutical precautions

Keep out of the reach and sight of children. Do not freeze. Do not use after the expiry date stated on the label and on the carton. Shelf-life after first opening the container: 28 days.

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

Disposal

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Legal category

POM-V

Packaging Quantities

1 glass vial containing 10ml.

Further information

Nil

Marketing Authorisation Holder (if different from distributor)

Le Vet B.V., The Netherlands

Marketing authorisation number

Vm 19994/4013.

Significant Changes

GTIN (Global Trade Item No)

10ml Vial:

08717973566175

