PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedastart 1 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Medetomidine hydrochloride 1.0 mg
(equivalent to 0.85 mg medetomidine)

Methyl parahydroxybenzoate (E 218)	1.0 mg
Propyl parahydroxybenzoate	0.2 mg

3. PACKAGE SIZE

10 ml
5 x 10 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Dogs:	Intramuscular or intravenous use.
Cats:	Intramuscular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}Once broached use within 28 days.

Once broached, use by …

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet. B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 19994/5009

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedastart 1 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Medetomidine hydrochloride 1 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached, use by

5. ROUTE(S) OF ADMINISTRATION

Dogs: IM, IV.
Cats: IM.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only. POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Sedastart is a clear colourless, sterile aqueous solution for injection containing:

Each ml contains:

Active substance:

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

Excipients:

Methyl parahydroxybenzoate(E218) 1.0 mg/ml
Propyl parahydroxybenzoate 0.2 mg/ml

3. TARGET SPECIES

Dogs and cats

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

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 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.

6. SPECIAL WARNINGS

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.

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.
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 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.

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 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.

Pregnancy and lactation:

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

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 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.

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 medetomidine hydrochloride 1 mg/ml, 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.

Major incompatibilities:

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

7. ADVERSE EVENTS

Target species: Cats and dogs.

Rare (1 to 10 animals / 10,000 animals treated):	Pulmonary oedema[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia, Hypertension[b], Death[c] , Respiratory depression[d], Cyanosis Vomit[e], Hyperaesthesia, Polyuria, Hypothermia, Muscle tremor, Hyperglycaemia[f]
Undetermined frequency (cannot be estimated from the available data)	Heart block 1st degree, Heart block 2nd degree, Extrasystole, Vasconstriction of coronary artery, Decreased cardiac output, Injection site pain.

[a] Especially in cats.
[b] Blood pressure will increase initially after administration and then return to normal, or slightly below normal
[c] from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported.
[d] In circulatory and respiratory depression manual ventilation and an oxygen supplement may be indicated
[e] Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery.
[f] In individual cases reversible hyperglycaemia due to depression of insulin secretion.

Atropine may increase the cardiac rate. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

The veterinary medicinal product is intended for:

Dogs: Intramuscular or intravenous use.
*Cats:*Intramuscular use.

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

Dogs:
For sedation the veterinary medicinal product should be administered at the rate of 750 µg medetomidine hydrochloride i.v. or 1000 µg medetomidine hydrochloride i.m. per square meter of body surface. 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 from 30-180 minutes.

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, the veterinary medicinal product should be administered at a dosage of 10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1 – 0.4 ml product 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 “Special warnings”.

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

For anaesthesia the veterinary medicinal product should be administered at a dosage of 80 µg medetomidine hydrochloride / kg bw (corresp. to 0.08 ml product / kg bw) and 2.5 to 7.5 mg 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. 40 µg medetomidine hydrochloride (corresp. to 0.04 ml product / kg bw) and 2.5 – 3.75 mg ketamine / kg bw) or 3.0 mg 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.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIODS

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and on the carton after Exp. The expiry date refers to the last day of that month. Once broached use within 28 days. When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number(s): Vm 19994/5009

Packaging:

1 x 1 glass vial with 10 ml.
5 x 1 glass vials with 10 ml.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Le Vet. B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands
Phone number: +44 (0)1939 211200

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:
Animalcare Ltd
Moorside
Monks Cross
York
YO32 9LB
United Kingdom
+44 (0)330 8189 717

17. OTHER INFORMATION

POM-V

For animal treatment only