PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedastart 1 mg/ml solution for injection
Medetomidine hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:

Active substance:
Medetomidine hydrochloride 1.0 mg
(equivalent to 0.85 mg medetomidine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
5 x 10 ml

5. TARGET SPECIES

Dogs and Cats.

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life after first broaching the vial: 28 days.
Once broached, use by …….

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedastart 1 mg/ml solution for injection
Medetomidine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE

Medetomidine hydrochloride 1 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs: IM, IV.
Cats: IM.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedastart 1 mg/ml solution for injection for cats and dogs
Active substance: Medetomidine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

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

4. INDICATION(S)

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 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.

6. 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.
In rare cases, pulmonary oedema has been reported, especially in cats. Death from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported.
Respiratory depression may occur, cyanosis.

In circulatory and respiratory depression manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate.
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. Pain at injection site and muscle tremor may be seen. In individual cases 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.

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 than 10 animals in 100 animals)
- uncommon (more than 1 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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Dog and cat.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 4.5.

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 PERIOD**

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 Shelf-life after first opening the container: 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 WARNING(S)

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 use in animals
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.

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.

Use during pregnancy, lactation or lay
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 (symptoms, emergency procedures, antidotes), if necessary
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<MM/YYYY>

15. OTHER INFORMATION

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