PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedastop 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Atipamezole hydrochloride 5.0 mg
(Equivalent to 4.27 mg of atipamezole)

3. PACKAGE SIZE

10 ml
5 x 10 ml
10 x 10 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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.
Keep the vial in the outer carton in order to protect from light.

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.

14. MARKETING AUTHORISATION NUMBERS

Vm 19994/4014

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedastop

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Atipamezole hydrochloride 5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp (mm/yyyy)

Once broached use within 28 days
Once broached, use by…….

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Sedastop 5 mg/ml solution for injection for cats and dogs.

2. Composition

Each ml contains:

Active substance:
Atipamezole hydrochloride 5.0 mg
(Equivalent to 4.27 mg of atipamezole)

Excipients:
Methyl parahydroxybenzoate (E 218) 1.0 mg

A clear colourless, sterile aqueous solution.

3. Target species

Dogs and cats.

4. Indications for use

Dogs and Cats:
Atipamezole hydrochloride is indicated for reversal of the sedative effects and cardiovascular effects after use of alpha-2- agonists like medetomidine and dexmedetomidine in dogs and cats.

5. Contraindications

Do not use in:
- Breeding animals
- Animals suffering from liver, renal or cardiac diseases

6. Special warnings

Special warnings:

Make sure the animal has regained a normal swallowing reflex before any food or drink is offered.

Special precautions for safe use in the target species:
After administration of the veterinary medicinal product, the animals should be allowed to rest in a quiet place. During recovery time animals should not be left unattended.
Due to different dosing recommendations caution should be taken if using the veterinary medicinal product off-label in animals other than the target species.
If other sedatives than medetomidine are given it must be kept in mind that the effects of those other agents may persist after reversal of (dex)medetomidine.
Atipamezole does not reverse the effect of ketamine, which may cause seizures in dogs and elicit cramps in cats when used alone. Do not use atipamezole earlier than 30-40 minutes after concomitant administration of ketamine.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Due to the potent pharmacological activity of atipamezole, skin-, eye- and mucous membrane- contact with this veterinary medicinal product should be avoided. In case of accidental spillage wash the affected area immediately with clean running water. Seek medical attention if irritation persists. Remove contaminated clothes that are in direct contact with the skin.
Care should be taken to avoid accidental ingestion or self-injection. In case of accidental ingestion or self-injection occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
The use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
A simultaneous administration of atipamezole with other centrally acting medicinal products such as diazepam, acepromazine or opiates is not recommended.

Overdose:
Overdose of atipamezole hydrochloride may result in transient tachycardia and over-alertness (hyperactivity, muscle tremor). If necessary, these symptoms may be reversed by a (dex)medetomidine hydrochloride dose which is lower than the usually used clinical dose.
If atipamezole hydrochloride is inadvertently administered to an animal not previously treated with (dex)medetomidine hydrochloride, hyperactivity and muscle tremor may occur. These effects may persist for about 15 minutes. Over-alertness in the cat is best handled by
minimizing external stimuli.

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

7. Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Hyperactivity, Vocalisation[a], Inappropriate urination, Inappropriate defecation Tachycardia Increased salivation, Vomiting Muscle tremor Increased respiratory rate
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension[b] Sedation[c], Recovery prolonged[d] Hypothermia[e]

[a] Atypical.

[b] Transient effect that has been observed during the first 10 minutes post-injection of atipamezole hydrochloride.

[c] Recurrence.

[d] The recovery time may not be shortened after administration of atipamezole.

[e] Only in cats, when using low doses to partially reverse the effects of medetomidine or dexmedetomidine. Should be guarded against, even when aroused from sedation.

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: https://www.gov.uk/report-veterinary-medicine-problem..

8. Dosage for each species, routes and method of administration

Intramuscular use.

Atipamezole hydrochloride is administered 15-60 min after medetomidine or dexmedetomidine hydrochloride administration.

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

Dogs: The intramuscular atipamezole hydrochloride dose [in µg] is five times that of the previous medetomidine hydrochloride dose or ten times that of the dexmedetomidine hydrochloride dose. Due to the 5-fold higher concentration of the active ingredient (atipamezole hydrochloride) in this veterinary medicinal product compared to that of preparations containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of preparations containing 0.5

mg dexmedetomidine hydrochloride, an equal volume of each preparation is required.

Dosage example Dogs:

Medetomidine 1 mg/ml solution for injection dosage	Narcostop 5 mg/ml solution for injection for dogs dosage
0.04 ml/kg body weight (bw), i.e. 40 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	Narcostop 5 mg/ml solution for injection for dogs dosage
0.04 ml/kg body weight (bw), i.e. 20 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw

Cats: The intramuscular atipamezole hydrochloride dose [in µg] is two-and-a-half times that of the previous medetomidine hydrochloride dose or five times that of the dexmedetomidine hydrochloride dose. Due to the 5-fold higher concentration of the active ingredient (atipamezole hydrochloride) in this veterinary medicinal product compared to that of preparations containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of preparations containing 0.5 mg dexmedetomidine hydrochloride, half the volume of the veterinary medicinal product to that of the previously administered medetomidine or dexmedetomidine should be given.

Dosage example Cats:

Medetomidine 1 mg/ml solution for injection dosage	Narcostop 5 mg/ml solution for injection for cats dosage
0.08 ml/kg body weight (bw), i.e. 80 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	Narcostop 5 mg/ml solution for injection for cats dosage
0.08 ml/kg body weight (bw), i.e. 40 µg/kg bw	0.04 ml/kg bw, i.e. 200 µg/kg bw

The recovery time is shortened to approximately 5 minutes. The animal becomes mobile after approximately 10 minutes after administration of the veterinary medicinal product.

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.
Keep the vial in the outer carton in order to protect from light.

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.

Shelf-life after first opening the immediate packaging:28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 19994/4014

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

15. PID link (Do not print heading)

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
Tel.: +31 348 563 434

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V	Veterinary medicinal product subject to prescription

Gavin Hall

Approved 26 January 2025