

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Sedastop 5 mg/ml solution for injection  
Atipamezole hydrochloride

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 ml solution for injection contains:

*Active substance:*

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

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

10 ml,  
5 x 10 ml  
10 x 10 ml

**5. TARGET SPECIES**

For dogs and cats.

**6. INDICATIONS**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Accidental injection is dangerous.

**10. EXPIRY DATE**

EXP:

Shelf life after first opening the container: 28 days.

Once broached, use by.....

**11. SPECIAL STORAGE CONDITIONS**

Do not freeze

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

**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**

Sedastop 5 mg/ml solution for injection  
Atipamezole hydrochloride

**2. QUANTITY OF THE ACTIVE SUBSTANCE**

Atipamezole hydrochloride 5 mg/ml<sup>3</sup>.      **CONTENTS BY WEIGHT, BY VOLUME OR  
BY NUMBER OF DOSES**

10 ml

**4. ROUTE(S) OF ADMINISTRATION**

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

Sedastop 5 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

Sedastop 5 mg/ml solution for injection for cats and dogs  
Active substance: Atipamezole hydrochloride

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

Sedastop is an aqueous solution for injection containing:

*Active substance:*

|  |           |
|--|-----------|
| Atipamezole hydrochloride              | 5.0 mg/ml |
| (Equivalent to 4.27 mg of atipamezole) |           |

*Excipients:*

|                                    |           |
|------------------------------------|-----------|
| Methyl parahydroxybenzoate (E 218) | 1.0 mg/ml |
|------------------------------------|-----------|

### 4. INDICATION(S)

*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. ADVERSE REACTIONS

A transient hypotensive effect has been observed during the first 10 minutes post-injection of atipamezole hydrochloride. In rare cases hyperactivity, tachycardia, salivation, atypical vocalization, muscle tremor, vomiting, increased respiratory rate, uncontrolled urination and uncontrolled defecation may occur.

In very rare cases recurrence of sedation may occur or the recovery time may not be shortened after administration of atipamezole.

In cats, when using low doses to partially reverse the effects of medetomidine or dexmedetomidine, the possibility of hypothermia (even when aroused from sedation) should be guarded against.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) 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 any other effects not mentioned in this leaflet, please inform your veterinary surgeon.”

## 7. TARGET SPECIES

Dogs and Cats

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For single intramuscular use.

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

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 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      | Sedastop 5 mg/ml solution for injection for dogs dosage |
| 0.04 ml/kg body weight (bw),<br>i.e. 40 µg/kg bw        | 0.04 ml/kg bw,<br>i.e. 200 µg/kg bw                     |
| Dexmedetomidine 0.5 mg/ml solution for injection dosage | Sedastop 5 mg/ml solution for injection for dogs dosage |
| 0.04 ml/kg body weight (bw),<br>i.e. 20 µg/kg bw        | 0.04 ml/kg bw,<br>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 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 product to that of the previously administered medetomidine or dexmedetomidine should be given.

Dosage example Cats:

|   |   |
|---|---|
| Medetomidine 1 mg/ml solution for injection dosage      | Sedastop 5 mg/ml solution for injection for cats dosage |
| 0.08 ml/kg body weight (bw),<br>i.e. 80 µg/kg bw        | 0.04 ml/kg bw,<br>i.e. 200 µg/kg bw                     |
| Dexmedetomidine 0.5 mg/ml solution for injection dosage | Sedastop 5 mg/ml solution for injection for cats dosage |
| 0.08 ml/kg body weight (bw),<br>i.e. 40 µg/kg bw        | 0.04 ml/kg bw,<br>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 product.

## 9. ADVICE ON CORRECT ADMINISTRATION

None

## 10. WITHDRAWAL PERIOD

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light. 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 immediate packaging: 28 days.

When the container is breached (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)**

### **Special precautions for use in animals**

After administration of the product, the animals should be allowed to rest in a quiet place. During recovery time animals should not be left unattended.

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

Due to different dosing recommendations caution should be taken if using the 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 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 to the physician.”

### **Use during pregnancy, lactation or lay**

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

The product should not be administered to pregnant and lactating bitches and queens

### **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 (symptoms, emergency procedures, antidotes), if necessary**

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.

### **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 products 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.

10 x 1 glass vial with 10 ml.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.