

sedastop[®] 5mg/ml

Solution for Injection for Cats and Dogs

Active substance: Atipamezole hydrochloride

Presentation: Sedastop is an aqueous solution for injection containing:

Active substance:

Atipamezole hydrochloride 5.0mg/ml
(equivalent to 4.27mg/ml of atipamezole)

Excipients:

Methyl parahydroxybenzoate (E 218) 1.0mg/ml

Indications

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.

Contraindications

Do not use in:

- breeding animals
- animals suffering from liver, renal or cardiac diseases.

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.

Target species

Dogs and cats.

Dosage, route and method of administration

For single intramuscular use.

Atipamezole hydrochloride is administered 15-60 minutes 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 1mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of preparations containing 0.5mg dexmedetomidine hydrochloride, an equal volume of each preparation is required.

Dosage example Dogs:

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

ml and the 10-fold higher concentration compared to that of preparations containing 0.5mg dexmedetomidine hydrochloride, half the volume of the product to that of the previously administered medetomidine or dexmedetomidine should be given.

Dosage example Cats:

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

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

Advice on correct administration

None.

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.

Special warnings

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 or lactation

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.

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.

Date on which the package leaflet was last approved

June 2015

Other information

1 x 1 glass vial with 10ml. 5 x 1 glass vials with 10ml. 10 x 1 glass vial with 10ml.

Not all pack sizes may be marketed.

Marketing authorisation holder:

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

Manufacturer for the batch release:

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

Distributed by:

Animalcare Ltd, 10 Great North Way, York, YO26 6RB, UK

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

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