

Sedastop 5mg/ml Solution for Injection for Cats and Dogs

Introduction



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Presentation

An aqueous solution for injection containing:

Active substance:

Atipamezole hydrochloride 5mg/ml (equivalent to 4.27mg of atipamezole)

Excipients:

Methyl parahydroxybenzoate (E 218) 1.0mg/ml

Uses

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.

Dosage and administration

For single intramuscular injection. 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 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 - dog dosage
0.04ml/kg bw, i.e. 40µg/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 - dog dosage
0.04ml/kg 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 - cat dosage
0.08ml/kg 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 - cat dosage
0.08ml/kg bw, i.e. 40µg/kg bw	0.04ml/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.

Contra-indications, warnings, etc

The product should not be used in breeding animals or animals suffering from liver or renal 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.

Special Warnings

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.

A simultaneous administration of atipamezole with other centrally acting medicinal products as diazepam, acepromazine or opiates is not recommended.

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.

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.

User warnings

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. If accidental ingestion or self-injection occurs, seek medical attention immediately, showing a copy of the package leaflet.

Pharmaceutical precautions

Keep out of the reach and sight of children. Keep the vial in the outer carton in order to protect from light. Do not freeze. Do not use after the expiry date stated on the label and on the carton. Shelf-life after first opening the immediate packaging: 28 days.

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

Disposal

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

Legal category

POM-V

Packaging Quantities

1 glass vial containing 10ml

Further information

Nil

Marketing Authorisation Holder (if different from distributor)

Le Vet B.V., The Netherlands

Marketing authorisation number

Vm 19994/4014.

Significant Changes

GTIN (Global Trade Item No)

10ml Vial:
08717973566205