

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ATIPAZOLE 5 mg/ml Solution for injection for dogs and cats
Atipamezole hydrochloride

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains:

Active substance:

Atipamezole4.27 mg
(as atipamezole hydrochloride 5.0 mg)

Excipients:

Methyl parahydroxybenzoate (E 218)1.0 mg

For the full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection.
Clear and colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and Cats.

4.2 Indications for use, specifying the target species

In dogs and cat: reversal of the sedative effects of medetomidine and dexmedetomidine

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in breeding animals.
Do not use in animals suffering from hepatic or renal or cardiac diseases.
See also section 4.7

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

After administration of the product, the animals should be allowed to rest in a quiet place. During the recovery phase, 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 using the product off label in animals other than the target species.

If other sedatives different than (dex)medetomidine are administered, it must be taken into account that the effects of these other agents are likely to persist after the reversal of the effects of (dex)medetomidine.

Atipamezole does not reverse the effect of ketamine, which can cause seizures in dogs and cause cramps in cats when used alone. Do not administer atipamezole within 30-40 minutes of prior administration of ketamine.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Due to the potent pharmacological activity of atipamezole, contact of the product with skin, eyes and mucous membranes 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 skin.

Care should be taken to avoid accidental ingestion or self-injection. In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive. The patient should not be left unattended.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

A transient hypotensive effect has been observed during the first ten minutes post-injection of atipamezole hydrochloride. Rare cases of hyperactivity, tachycardia, salivation, abnormal vocalization, muscle tremors, vomiting, increased respiratory rate, uncontrolled urination and uncontrolled defecation were observed. Very rare

cases of recurrent sedation may occur or the recovery time may not be shortened after the 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 treated displaying adverse reaction(s)).
- Common (more than 1 but less than 10 animals in 100 animals treated).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated).
- Rare (more than 1 but less than 10 animals in 10,000 animals treated).
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been established during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amount(s) to be administered and administration route

For single intramuscular use.

The dose depends on the previously administered medetomidine or dexmedetomidine dose. Atipamezole hydrochloride is administered 15 – 60 min after medetomidine or dexmedetomidine hydrochlorid injection.

Dogs: The dose of atipamezole hydrochloride (in µg per kg of body weight) is five times that of the previous dose of medetomidine hydrochloride or ten times that of the dose of dexmedetomidine hydrochloride.

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 concentration compared to that preparations containing 0.5 mg dexmedetomidine hydrochloride, an equal volume of each preparation is required. Due to the 50-fold concentration compared to that preparations containing 0.1 mg dexmedetomidine hydrochloride, a volume 5 times lower of the atipamezole preparation is required.

Dosage example dogs

Medetomidine 1.0 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0mg/ml solution for injection dosage
0.04 ml/kg body weight (bw), corresponding with 40 µg/kg bw	0.04 ml/kg body weight (bw), corresponding with 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0mg/ml solution for injection

dosage	
0.04 ml/kg body weight (bw), corresponding with 20 µg/kg bw	0.04 ml/kg body weight (bw), corresponding with 200 µg/kg bw
Dexmedetomidine 0.1 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0mg/ml solution for injection dosage
0.2 ml/kg body weight (bw), corresponding with 20 µg/kg bw	0.04 ml/kg body weight (bw), corresponding with 200 µg/kg bw

Cats: The dose of atipamezole hydrochloride (in µg per kg of body weight) is 2.5 times that of the previous dose of medetomidine hydrochloride or 5 times that of the dose of dexmedetomidine hydrochloride. Due to the 5-fold 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 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. Due to the 50-fold concentration compared to that preparations containing 0.1 mg dexmedetomidine hydrochloride, a volume 10 times lower of the atipamezole preparation is required.

Dosage example cats:

Medetomidine 1.0 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0mg/ml solution for injection dosage
0.08 ml/kg body weight (bw), corresponding with 80 µg/kg bw	0.04 ml/kg body weight (bw), corresponding with 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0mg/ml solution for injection dosage
0.08 ml/kg body weight (bw), corresponding with 40 µg/kg bw	0.04 ml/kg body weight (bw), corresponding with 200 µg/kg bw
Dexmedetomidine 0.1 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0mg/ml solution for injection dosage
0.4 ml/kg body weight (bw), corresponding with 40 µg/kg bw	0.04 ml/kg body weight (bw), corresponding with 200 µg/kg bw

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose of atipamezole hydrochloride may result in transient tachycardia and over-alertness (hyperactivity, muscle tremors). If necessary, these signs may be reversed by a medetomidine or dexmedetomidine hydrochloride dose which is lower than usually used clinically.

If atipamezole hydrochloride is inadvertently administered to an animal not previously treated with medetomidine or dexmedetomidine hydrochloride, hyperactivity and muscle tremors may occur. These effects may persist for about 15 minutes.

Over-alertness in the cat is best handled by minimizing external stimuli.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: α 2-receptor antagonist (Antidote)
ATC Vet Code: QV03AB90

5.1 Pharmacodynamic properties

Atipamezole is a selective and potent agent which blocks the α -2 receptors (α -2 antagonist) which induces the release of a neurotransmitter, noradrenalin, in central and peripheral nervous system which results in an activation of the central nervous system through sympathetic activation. Other pharmacodynamic effects that may be observed, such as influence on the cardiovascular system, for example, are light. However, a transient decrease in blood pressure may be observed in the first 10 minutes after the injection of atipamezole hydrochloride.

As α -2 antagonist, atipamezole is capable of eliminating (or inhibiting) the effects of the α -2 receptor agonists such as medetomidine or dexmedetomidine. Likewise, atipamezole reverses the sedative effects of (dex)medetomidine hydrochloride in dogs and cats, whose condition returns to normal and may cause a transient increase in the heart rate.

5.2 Pharmacokinetic particulars

Atipamezole hydrochloride is quickly absorbed after intramuscular injection. It is also quickly and completely metabolised. Metabolites are excreted mainly in urine and faeces in small amounts.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Sodium Chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
No special storage conditions of medicinal product are required after first opening the container.

6.5 Nature and composition of immediate packaging

Colourless glass type I vial containing 10 ml which is fitted with a bromobutyl rubber stopper sealed with aluminium caps with plastic flip-off.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.
C/ Les Corts, 23
08028 Barcelona
Spain

8. MARKETING AUTHORISATION NUMBER(S)

Vm 32509/4012

9. DATE OF FIRST AUTHORISATION

23 October 2013

10. DATE OF REVISION OF THE TEXT

August 2018


PROHIBITION OF SALE, SUPPLY AND/OR USE

[ES]

Supplied only on veterinary prescription
Administered only by a veterinary surgeon

Revised: August 2018
AN: 01963/2017

Approved: 10 August 2018

A handwritten signature in black ink, appearing to read 'J. Long'.