

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ATIPAZOLE 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Atipamezole.....4.27 mg
(as atipamezole hydrochloride 5.0 mg)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E 218)	1.0 mg
Sodium chloride	
Water for injections	

Clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Reversal of the sedative effects of medetomidine and dexmedetomidine.

3.3 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 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

After administration of the veterinary medicinal 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.

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 onto skin, wash the affected area immediately with clean running water. Seek medical advice if irritation persists and show the package leaflet or the label to the physician. 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Hyperactivity, impaired vocalisation Tachycardia Hypersalivation, vomiting, involuntary defecation Muscle tremor Involuntary urination Increased respiratory rate
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension ¹ . Sedation ² , recovery prolonged ² Hypothermia ³

¹ Transient, during the first ten minutes post-injection.

² Recurrent sedation may occur, or the recovery time may not be shortened after the administration of atipamezole.

³ 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy and lactation

The use is not recommended during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use. For single injection.

The dose depends on the previously administered medetomidine or dexmedetomidine dose.

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 veterinary medicinal product compared to those preparations containing 1 mg medetomidine hydrochloride per ml, and the 10-fold concentration compared to those preparations containing 0.5 mg dexmedetomidine hydrochloride, an equal volume of each preparation is required. Due to the 50-fold concentration compared to those 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 veterinary medicine product compared to those preparations containing 1 mg medetomidine hydrochloride per ml and the 10-fold concentration compared to those 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 those 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

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration only by a veterinarian.

3.12 Withdrawal period(s)

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QV03AB90

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 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.

5.4 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.

Pack size:

Carton box with 1 vial of 10 ml

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.

7. MARKETING AUTHORISATION NUMBER

Vm 32509/4012

8. DATE OF FIRST AUTHORISATION

23 October 2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 11 February 2025