SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atipam, 5.0 mg/ml, solution for injection for cats and dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active ingredients	
Atipamezole hydrochloride	5.0 mg
(equivalent to 4.27 mg atipamezole base)	
Excipients	
Methyl parahydroxybenzoate (E 218)	1.0 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear and colourless sterile aqueous solution.

4. CLINICAL PARTICULARS

4.1. Target species

Cats and dogs.

4.2. Indications for use, specifying the target species

Atipamezole hydrochloride is a selective α2-antagonist and is indicated for reversal of the sedative effects of medetomidine and dexmedetomidine in cats and dogs.

4.3. Contraindications

The product should not be used in:
- Breeding animals
- Animals suffering from liver- or renal diseases

See also section 4.7.

4.4. Special warnings for each target species

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

4.5. Special precautions for use

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.
Due to different dosing recommendations caution should be taken if using the product off-label in animals other than the target species.
If sedatives other than (dex)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 administer atipamezole within 30 – 40 minutes of prior 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 contact of the product with skin or eyes rinse abundantly with fresh 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, seek medical advice immediately and show the package leaflet to the physician.

4.6. Adverse reactions (frequency and seriousness)

A transient hypotensive effect has been observed during the first 10 minutes post-injection of atipamezole hydrochloride. In rare cases hyperactivity, tachycardia, salivation, atypical vocalisation, 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.

4.7. Use during pregnancy or lactation.

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

4.8. Interactions with other veterinary medicinal products and other forms of interaction

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

4.9. Amounts to be administered and administration route

For single intramuscular injection in cats and dogs. Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes. Atipamezole is generally administered 15 - 60 minutes after the medetomidine or dexmedetomidine injection.

Dogs: The 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 1.0 mg/ml solution for injection dosage	**Atipam 5.0 mg/ml solution for injection dosage**
0,04 ml/kg body weight (bw), i.e. 40 µg/kg bw	0,04 ml/kg body weight (bw), i.e. 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	**Atipam 5.0 mg/ml solution for injection dosage**
0,04 ml/kg body weight (bw), i.e. 20 µg/kg bw	0,04 ml/kg body weight (bw), i.e. 200 µg/kg bw

Cats: The 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 1.0 mg/ml solution for injection dosage	**Atipam 5.0 mg/ml solution for injection dosage**
0,08 ml/kg body weight (bw), i.e. 80 µg/kg bw	0,04 ml/kg body weight (bw), i.e. 200 µg/kg bw
Dexmedetomidine 0.5 mg/ml solution for injection dosage	**Atipam 5.0 mg/ml solution for injection dosage**
0,08 ml/kg body weight (bw), i.e. 40 µg/kg bw	0,04 ml/kg body weight (bw),, i.e. 200 µg/kg bw

The recovery time is shortened to approximately 5 minutes. The animals become mobile after 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 tremor). If necessary, these symptoms may be reversed by a 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.

4.11. Withdrawal periods

Not applicable

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QV03AB90
Pharmacotherapeutic group: α2-receptor antagonist (Antidote)

5.1. Pharmacodynamic properties

Atipamezole is a potent and selective α2-receptor blocking agent (α2-antagonist), which promotes the release of the neurotransmitter noradrenaline in the central as well as in the peripheral nervous systems. This leads to activation of the central nervous system due to sympathetic activation. Other pharmacodynamic effects such as impact on the cardiovascular system, are mild, although a transient decrease in blood pressure may occur within the first 10 minutes following administration of atipamezole hydrochlodride. As a α2-antagonist, atipamezole is capable of eliminating (or inhibiting) the effects of the α2-receptor agonist, medetomidine or dexmedetomidine. Thus atipamezole reverses the sedative effects of (dex)medetomidine hydrochloride in cats and dogs to normal and may lead to a transient increase in heart rate.

5.2. Pharmacokinetic particulars

Atipamezole hydrochloride is rapidly absorbed after intramuscular injection. The maximal concentration in the central nervous system is reached in 10-15 minutes. Volume of distribution (V_d) is about 1 – 2.5 l/kg. The half-life ($t_{½}$) of atipamezole hydrochloride is reported to be approximately 1 hour. Atipamezole hydrochloride is rapidly and completely metabolised. The metabolites are mainly excreted in urine with a small amount excreted in faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E 218),
Sodium chloride,
Sodium hydroxide (for pH adjustment),
Hydrochloric acid (for pH adjustment),
Water for injections

6.2. Incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products in the same syringe.
See also section 4.8.

6.3. Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:	3 years
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.

6.5. Nature and composition of immediate packaging

Cardboard box with 1 clear glass type I vial of 5, 10 or 20 ml, with a teflon coated halogenated rubber stopper and aluminium cap. Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.,
Handelsweg 25,
5531 AE Bladel,
The Netherlands.

8. MARKETING AUTHORISATION NUMBER

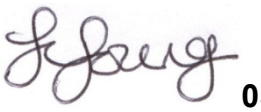
Vm 16849/4011

9. DATE OF FIRST AUTHORISATION

04 March 2008

10. DATE OF REVISION OF THE TEXT

June 2013

Approved:  **05/06/2013**