

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX/5
ML, 10 ML and 20 ML}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atipam 5.0 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Atipamezole hydrochloride 5.0 mg
(equivalent to 4.27 mg atipamezole base)

3. PACKAGE SIZE

5 ml

10 ml

20 ml

4. TARGET SPECIES

Dogs and cats.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 16849/4011

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {VIAL LABEL/5 ML AND 10 ML AND 20 ML}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atipam



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Atipamezole hydrochloride 5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Atipamezole hydrochloride 5.0 mg

Excipients:

Methyl parahydroxybenzoate (E 218) 1.0 mg

Clear and colourless aqueous solution.

3. Target species

Dogs and cats.

4. Indications for use

Atipamezole hydrochloride is a selective α 2-antagonist and indicated for reversal of the sedative effects of medetomidine and dexmedetomidine in cats and dogs.

5. Contraindications

Do not use in breeding animals
Do not use in animals suffering from liver- or renal diseases.
See also section 'Special Warnings'.

6. Special warnings

Special warnings:

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

Special precautions for safe use in the target species:

After administration of the veterinary medicinal 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 veterinary medicinal product off-label in animals other than the target species. If sedatives other 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 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 veterinary medicinal product should be avoided. In case of accidental contact of the veterinary medicinal 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.

Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:

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

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 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.

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.

7. Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Hyperactivity, Vocalisation ^a , Involuntary urination, Involuntary defecation Tachycardia Increased salivation, Vomiting Muscle tremor Increased respiratory rate
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension ^b Sedation ^c , Recovery prolonged ^d Hypothermia ^e

^a Atypical.

^b Transient effect that has been observed during the first 10 minutes post-injection of atipamezole hydrochloride.

^c Recurrence.

^d The recovery time may not be shortened after administration of atipamezole.

^e In cats, when using low doses to partially reverse the effects of medetomidine or dexmedetomidine. Should be guarded against, even when aroused from sedation.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem>.

8. Dosage for each species, routes and method of administration

For single intramuscular use 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product.

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 16849/4011

Cardboard box with 1 glass vial of 5, 10 or 20 ml, with a rubber stopper and cap.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Local representatives and contact details to report suspected adverse reactions:
Dechra Veterinary Product Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0)1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V	Veterinary medicinal product subject to prescription
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Gavin Hall
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