PART I B 2

LABELING AND PACKGAGE LEAFLET

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

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:
Active substances:
Atipamezole hydrochloride 5.0 mg
Excipients:
Methyl parahydroxybenzoate (E 218) 1.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5, 10, 20 ml

5. TARGET SPECIES

Cats and dogs

6. INDICATIONS

----- *(Not mandatory)*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Not applicable

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY *{National item}*

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

{Number allocated by MS}

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
5 and 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE

----- *(Not mandatory if mentioned in 1)*

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 / 10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection

5. WITHDRAWAL PERIOD

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6. BATCH NUMBER

Lot{number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Read the package leaflet before use.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:
Active substances:
Atipamezole hydrochloride 5.0 mg
Excipients:
Methyl parahydroxybenzoate (E 218) 1.0 mg

3. PHARMACEUTICAL FORM

---- (Stated in the name)

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

---- (Stated in the name)

6. INDICATIONS

----- *(Not mandatory)*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection.
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8. WITHDRAWAL PERIOD

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9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

Not applicable

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

----- (*Not possible to include a phrase due to the size of the label)*

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

{*Number allocated by MS}*

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Other items
Keep the container in the outer carton

B. PACKAGE LEAFLET

PACKAGE LEAFLET
ATIPAM 5.0 mg/ml, solution for injection for cats and dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml clear and colourless aqueous solution for injection contains:
Active substances:
Atipamezole hydrochloride 5.0 mg
(equivalent to 4.27 mg atipamezole base)
Excipients:
Methyl parahydroxybenzoate (E 218) 1.0 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

See also section 12.

6. 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 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon or pharmacist.

7. TARGET SPECIES

Cats and dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 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 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 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Keep out of the reach and sight of children.
Do not use after the expiry date stated on the label after EXP
Shelf-life after first opening the container: 28 days.
Any remaining content of the product should be disposed of after this period.

12. SPECIAL WARNING(S)

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

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.

Use during pregnancy and 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.

Interactions with other 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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2012

15. OTHER INFORMATION

Pack sizes: 5, 10 or 20 ml.

Not all pack sizes may be marketed {National item}

Blue Box Requirements