LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution contains:

Active substance:
Atipamezole .....4.27 mg
(as atipamezole hydrochloride 5.0 mg)

Excipients:
Methyl parahydroxybenzoate (E 218).....1.0 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs and Cats

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry date {month/year}
Once opened, use by…
Shelf-life after first opening the vial: 28 days
[PL] Termin ważności (EXP)

11. SPECIAL STORAGE CONDITIONS

Not applicable

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

Disposal: read package leaflet

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.

[PL]
Wyłącznie dla zwierząt.
Wydawany z przepisu lekarza – Rp. Do podawania pod nadzorem lekarza weterynarii.

[FR]
Délivrance interdite au public.
Administration réservée exclusivement aux vétérinaires.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L.
C/ Les Corts, 23
08028 Barcelona
Spain

[IT]
Manufacturer responsible for batch release:
LABIANA LIFE SCIENCES, S.A.
C/ Venus, 26, Pol. Ind. Can Parellada,
Terrasa, 08228 Barcelona
SPAIN

Distributed by:
Forte Healthcare Ltd
Cougar Lane
Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32509/4012

17. MANUFACTURER’S BATCH NUMBER

Batch {number}
[PL] Nr serii (LOT

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE

Atipamezole hydrochloride 5.0 mg/ml

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD(S)

Not applicable.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

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

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L.
C/ Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for batch release:
LABIANA LIFE SCIENCES, S.A.
C/ Venus, 26, Pol. Ind. Can Parellada,
Terrasa, 08228 Barcelona
SPAIN

Distributed by
Forte Healthcare Ltd
Cougar Lane
Naul
Co. Dublin
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml of solution contains:

Active substance:
Atipamezole.....4.27 mg
(as atipamezole hydrochloride 5.0 mg)

Excipients:
Methyl parahydroxybenzoate (E 218).....1.0 mg

Clear and colourless solution.

4. INDICATIONS

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

5. 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 section “Special warnings”.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and Cats

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

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.
Shelf-life after first opening the container: 28 days.
Do not use after the expiry date stated on the carton and label.
Discard any product remaining in the container after 28 days of the first opening.
No special storage conditions of medicinal product are required after first opening the container.

12. SPECIAL WARNINGS

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.

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.

Pregnancy and lactation

The safety of the 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

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

Overdose (symptoms, emergency procedures, antidotes)

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

If atipamezole hydrochloride is inadvertently administered to an animal not previously treated with medetomidine or dexemedetomidine 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.

Incompatibilities

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Box with 1 vial of 10ml.

[FR]
Délivrance interdite au public.
Administration réservée exclusivement aux vétérinaires.

Approved: 10 August 2018