

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

**REVERSE 5 mg/ml solution for injection for dogs and cats (ES, PT)
ATIDORM 5 mg/ml solution for injection for dogs and cats (IT)**

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

Marketing authorisation holder:

FATRO S.p.A.
Via Emilia, 285
40064, Ozzano dell'Emilia (BO)
Italy

Manufacturer responsible for batch release:

LABIANA LIFE SCIENCES, S.A.
C/ Venus, 26, Pol. Ind. Can Parellada,
Terrasa, 08228 Barcelona
Spain

Distributed by:

To be completed nationally.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

REVERSE 5 mg/ml solution for injection for dogs and cats (ES, PT)
ATIDORM 5 mg/ml solution for injection for dogs and cats (IT)
Atipamezole hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:

Atipamezole 4.27 mg
(equivalent to atipamezole hydrochloride 5.0 mg)

Excipients:

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

Clear and colourless solution.

4. INDICATION(S)

To reverse the sedative effects produced by medetomidine or dexmedetomidine in dogs and cats in order to recover the animal.
To reverse the possible overdose of medetomidine.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals suffering from hepatic or renal or cardiac diseases or poor health status.

See also pregnancy and lactation subsection at point 12.

6. ADVERSE REACTIONS

In very rare cases, the following clinical signs may be observed:

- Cardiovascular: tachycardia, slight transient decrease of arterial pressure during the first ten minutes post-injection
- Respiratory: increased respiratory rate, dyspnea
- Digestive: uncontrolled defecation, vomiting, diarrhea
- Urinary: uncontrolled urination
- Behaviour: hyperactivity, abnormal vocalization
- Neurological: hypersalivation, muscle tremors. 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.

Dogs: The dose of atipamezole hydrochloride (in $\mu\text{g}/\text{kg}$ 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/ml medetomidine hydrochloride, and the 10-fold concentration compared to that preparations containing 0.5 mg/ml dexmedetomidine hydrochloride, an equal volume of each preparation is required. Due to the 50-fold concentration compared to that preparations containing 0.1 mg/ml dexmedetomidine hydrochloride, a volume 5 times lower of the atipamezole preparation is required.

Dosage example in dogs:

Medetomidine 1.0 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0 mg/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 5.0 mg/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 5.0 mg/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/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/ml medetomidine hydrochloride and the 10-fold concentration compared to that of preparations containing 0.5 mg/ml 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/ml dexmedetomidine hydrochloride, a volume 10 times lower of the atipamezole preparation is required.

Dosage example in cats:

Medetomidine 1.0 mg/ml solution for injection dosage	Atipamezole hydrochloride 5.0 mg/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 5.0 mg/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 5.0 mg/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

In dogs and cats, atipamezole hydrochloride is administered 15-60 min after medetomidine or dexmedetomidine hydrochloride injection.

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.

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

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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 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, 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:

Concurrent use of atipamezole with other drugs affecting the Central nervous system (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 signs may 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 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.

Incompatibilities:

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

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

Any unused veterinary medicinal product or waste materials 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

To be completed nationally.

15. OTHER INFORMATION

Package size:

Cardboard box with 1 vial of 10 ml.

(For Spain only, include:

For animal treatment only – to be supplied only on veterinary prescription.

Administration only by a veterinary surgeon.)