

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 vial of 10 ml

1. 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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Atipamezole 4.27 mg

(equivalent to atipamezole hydrochloride 5.0 mg)

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

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

EXP {month/year}

Once broached use within 28 days.

Once broached use by

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.

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

FATRO S.p.A.

Via Emilia, 285

40064, Ozzano dell'Emilia (BO)

Italy

16. MARKETING AUTHORISATION NUMBER

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml label

1. 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

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains:

Active substance:

Atipamezole 4.27 mg
(equivalent to atipamezole hydrochloride 5.0 mg)

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD**6. BATCH NUMBER**

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.
Once broached use by

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

