

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 5 vials of 5 ml

10 vials of 5 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ANTISHMANIA 300 mg/ml solution for injection for dogs (ES, EL).

ANTISHMANIA solution for injection for dogs (FR)

Meglumine antimoniate

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

(ES, EL)

Each ml contains:

Active substance: Meglumine antimoniate 300 mg (equivalent to Antimony 81 mg) - **Excipients:** Potassium metabisulfite (E224) 1.6 mg - Sodium sulfite, anhydrous (E221) 0.18 mg.

(FR)

Each ml contains:

Active substance: Antimony 81 mg (equivalent to Meglumine antimoniate 300 mg) - **Excipients:** Potassium metabisulfite (E224) - Sodium sulfite anhydrous (E221).

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

5 x 5 ml

10 x 5 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Treatment of canine leishmaniasis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month /year}
Once opened, use immediately

11. SPECIAL STORAGE CONDITIONS

Store below 25°C.

12. 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.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

Veterinary medicinal product subject to 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
Ozzano Emilia - Bologna
Italy

16. MARKETING AUTHORISATION NUMBERS

17. MANUFACTURER’S BATCH NUMBER

Batch n.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
5 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ANTISHMANIA 300 mg/ml solution for injection for dogs (ES, EL).
ANTISHMANIA solution for injection for dogs (FR)

Meglumine antimoniate

2. QUANTITY OF ACTIVE SUBSTANCE

(ES, EL) Each ml contains: Meglumine antimoniate 300 mg (equivalent to Antimony 81 mg).

(FR) Each ml contains: Antimony 81 mg (equivalent to Meglumine antimoniate 300 mg)

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

5 ml

4. ROUTE(S) ADMINISTRATION

Subcutaneous use.

5. WITHDRAWAL PERIODS

6. BATCH NUMBER

Batch n.

7. EXPIRY DATE

EXP {month /year}
Once opened, use immediately

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"