

ANTISHMANIA, 300 mg/ml, solution for injection for dogs.

Authorised

- Meglumine antimonate

Product identification

Medicine name:

ANTISHMANIA, 300 mg/ml, solution for injection for dogs.

ANTISHMANIA 300 MG/ML SOLUTION INJECTABLE POUR CHIENS

Active substance:

Meglumine antimonate

Target species:

Dog

Route of administration:

Subcutaneous use

Product details

Active substance and strength:

Meglumine antimonate

300.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QP51DX01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

France

Package description:

box containing 5 vials of 5 ml

box containing 10 vials of 5 ml

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

Fatro S.p.A.

Marketing authorisation date:

29/01/2016

Manufacturing sites for batch release:

Fatro S.p.A.

Responsible authority:

French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:

FR/V/7989990 5/2016

Date of authorisation status change:

5/11/2020

Reference member state:

Spain

Procedure number:

ES/V/0232/001

Concerned member states:

France Greece

To consult adverse reactions on veterinary medicinal products please go to

www.adrreports.eu/vet

Documents

Summary of Product Characteristics

English (PDF)

Published on: 11/04/2023

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Package Leaflet

Labelling

Package Leaflet and Labelling

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Combined File of all Documents

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