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Milteforan 20 mg/ml oral solution for dogs

Authorised

- Miltefosine

Product identification

Medicine name:
Milteforan 20 mg/ml oral solution for dogs

Active substance:
Miltefosine

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Miltefosine
20.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP51DX07

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
France

Available in:
France

Package description:
Carton box containing a 30 ml Polyethylene terephthalate (PET) bottle equipped with a sampling polypropylene (PP) snap cap with silicone stopper and a 3 ml polypropylene (PP) syringe graduated every 0.1 ml
Carton box containing a 60 ml Polyethylene terephthalate (PET) bottle equipped with a sampling polypropylene (PP) snap cap with silicone stopper and a 3 ml polypropylene (PP) syringe graduated every 0.1 ml
Carton box containing a 90 ml Polyethylene terephthalate (PET) bottle equipped with a sampling polypropylene (PP) snap cap with silicone stopper and a 3 ml polypropylene (PP) syringe graduated every 0.1 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Virbac

Marketing authorisation date:
28/02/2024

Manufacturing sites for batch release:
Virbac

Responsible authority:
French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:
FR/V/9024384 6/2024

Date of authorisation status change:
28/02/2024

Reference member state:
Netherlands

Procedure number:
NL/V/0405/001

Concerned member states:
Bulgaria Croatia Cyprus France Greece Italy Portugal Romania Slovenia Spain

Generic of:
600000004401

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet and Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

NLV0405001DC Milteforan final PuAR.pdf