

Itrafungol 10 mg/ml Oral Solution

Authorised

- Itraconazole

Product identification

Medicine name:

Itrafungol 10 mg/ml Oral Solution

Active substance:

Itraconazole

Target species:

Cat

Route of administration:

Oral use

Product details

Active substance and strength:

Itraconazole
10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Oral solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ02AC02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Norway

Available in:

Norway

Package description:

Amber glass bottle (type III) containing 52 ml oral solution, closed with a child resistant polypropylene screw cap with a LDPE insert packed in a cardboard box with a graduated dosing syringe.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Virbac

Marketing authorisation date:

12/11/2004

Manufacturing sites for batch release:

Lusomedicamenta Sociedade Tecnica Farmaceutica S.A.

Responsible authority:

Norwegian Medical Products Agency

Authorisation number:

04-2575

Date of authorisation status change:

15/09/2021

Reference member state:

Ireland

Procedure number:

IE/V/0431/001

Concerned member states:

Austria Belgium Czechia Denmark Finland France Germany Greece
Hungary Italy Luxembourg Netherlands Norway Portugal Spain Sweden
United Kingdom (Northern Ireland)

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www.adrreports.eu/vet

Documents

Summary of Product Characteristics

English (PDF)

Published on: 17/11/2024

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Package Leaflet

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Combined File of all Documents