Felimazole 5 mg/ml oral solution for cats

Authorised

- Thiamazole

Product identification

Medicine name:
Felimazole 5 mg/ml oral solution for cats

Active substance:
Thiamazole

Target species:
Cat

Route of administration:
Oral use

Product details

Active substance and strength:
Thiamazole
5.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QH03BB02

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

Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
Polyethylene terephthalate (PET) amber bottle of 30 ml, closed with a low density polyethylene (LDPE) plug and a high density polyethylene (HDPE) closure. The veterinary medicinal product is supplied with a 1 ml polyethylene (PE) / polypropylene (PP) measuring syringe for administration of the solution to the animal. The syringe is graduated in 0.25 mg increments up to 5 mg. Each closed bottle and accompanying syringe is contained in a cardboard carton.
Polyethylene terephthalate (PET) amber bottle of 100 ml, closed with a low density polyethylene (LDPE) plug and a high density polyethylene (HDPE) closure. The veterinary medicinal product is supplied with a 1 ml polyethylene (PE) / polypropylene (PP) measuring syringe for administration of the solution to the animal. The syringe is graduated in 0.25 mg increments up to 5 mg. Each closed bottle and accompanying syringe is contained in a cardboard carton.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - known active substance (Article 8 of Regulation (EU) 2019/6)

Marketing authorisation holder:

Dechra Regulatory B.V.

Marketing authorisation date:
18/12/2023

Manufacturing sites for batch release:
Genera d.d.

Responsible authority:
Danish Medicines Agency

Authorisation number:
68669

Date of authorisation status change:
18/12/2023

Reference member state:
Ireland

Procedure number:
IE/V/0505/004

Concerned member states:
Austria Belgium Bulgaria Croatia Czechia Denmark Finland France Germany Greece Hungary Italy Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden

United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

English (PDF)

Published on: 3/05/2024

Download

Combined File of all Documents