Amcofen 2.5 mg/25 mg film-coated tablets for small dogs and puppies weighing at least 0.5 kg

Authorised

- Milbemycin oxime
- Praziquantel

Product identification

Medicine name:
Amcofen 2.5 mg/25 mg film-coated tablets for small dogs and puppies weighing at least 0.5 kg

Active substance:
Milbemycin oxime

Praziquantel

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Milbemycin oxime

2.50 milligram(s) / 1.00 Tablet

Praziquantel
25.00 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Film-coated tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP54AB51

Legal status of supply:
Veterinary medicinal product not subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Lithuania

Available in:
Lithuania

Package description:
Blister packs consisting of cold formed aluminium foil which consists of aluminum layer coated with OPA (Oriented Polyamide) film on one side and PVC on the other side and an aluminum sealing foil. Package sizes:Cardboard box with 12 blisters, each blister contains 4 tablets (total 48 tablets).
Blister packs consisting of cold formed aluminium foil which consists of aluminum layer coated with OPA (Oriented Polyamide) film on one side and PVC on the other side and an aluminum sealing foil. Package sizes:Cardboard box with 1 blister of 4 tablets.
Blister packs consisting of cold formed aluminium foil which consists of aluminum layer coated with OPA (Oriented Polyamide) film on one side and PVC on the other side and an aluminum sealing foil. Package sizes:Cardboard box with 1 blister of 2 tablets.

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:
KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:
16/08/2021

Manufacturing sites for batch release:
Krka-Farma d.o.o.
KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:
State Food And Veterinary Service

Authorisation number:
LT/2/21/2678/001-003

Date of authorisation status change:
25/06/2024

Reference member state:
Ireland

Procedure number:
IE/V/0524/003

Concerned member states:
Belgium Bulgaria Croatia Czechia Estonia France Germany Hungary Italy Latvia Lithuania Netherlands Poland Portugal Romania Slovakia Slovenia Spain United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

Combined File of all Documents

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