Amcofen 12.5 mg/125 mg film-coated tablets for dogs weighing at least 5 kg

Authorised

- Milbemycin oxime
- Praziquantel

Product identification

Medicine name:
Amcofen 12.5 mg/125 mg film-coated tablets for dogs weighing at least 5 kg

Active substance:
Milbemycin oxime

Praziquantel

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Milbemycin oxime
12.50 milligram(s) / 1.00 Tablet

Praziquantel
125.00 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Film-coated tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP54AB51

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

Authorisation status:
Valid

Authorised in:
Poland

Available in:
Poland

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:
29/10/2021

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

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
3145

Date of authorisation status change:
29/10/2021

Reference member state:
Ireland

Procedure number:
IE/V/0524/004

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

Package Leaflet

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

Labelling

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

Summary of Product Characteristics

English (PDF)
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