Amcofen 2.5 mg/25 mg chewable 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 chewable tablets for small dogs and puppies weighing at least 0.5 kg
AMCOFEN 2,5 mg/25 mg comprimate masticabile pentru cainii de talie mica si catei cu greutate de cel putin 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:
Chewable tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP54AB51

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

Authorisation status:
Valid

Authorised in:
Romania

Package description:
Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil.Cardboard box with 1 blister of 2 tablets.
Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil.Cardboard box with 1 blister of 4 tablets.
Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil.Cardboard box with 12 blisters, each blister contains 4 tablets (total 48 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:
18/06/2019

Manufacturing sites for batch release:
TAD Pharma GmbH
KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
240085

Date of authorisation status change:
18/06/2024

Reference member state:
Ireland

Procedure number:
IE/V/0524/001

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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