Aderexa 12.5 mg/125 mg chewable tablets for dogs weighing at least 5 kg

Authorised

- Milbemycin oxime
- Praziquantel

Product identification

Medicine name:
Aderexa 12.5 mg/125 mg chewable tablets for dogs weighing at least 5 kg
Aderexa 12.5 mg/125 mg chewable 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:
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:
Ireland

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:

27/07/2018

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

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10774/063/002

Date of authorisation status change:
27/07/2018

Reference member state:
Ireland

Procedure number:
IE/V/0528/002

Concerned member states:
United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics