

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

Authorised

- Milbemyacin oxime
- Praziquantel

Product identification

Medicine name:

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

Active substance:

Milbemyacin oxime

Praziquantel

Target species:

Dog

Route of administration:

Oral use

Product details

Active substance and strength:

Milbemyacin oxime

12.50 milligram(s) / 1.00 Tablet

Praziquantel

125.00 milligram(s) / 1.00 Tablet

Pharmaceutical form:

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:

Netherlands

Available in:

Netherlands

Package description:

Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil. Box with 12 blisters, each blister contains 4 tablets.

Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil. Box with 1 blister of 4 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:

24/09/2019

Manufacturing sites for batch release:

Krka-Farma d.o.o.
KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:

Medicines Evaluation Board

Authorisation number:

REG NL 114740

Date of authorisation status change:

27/01/2022

Reference member state:

Ireland

Procedure number:

IE/V/0463/002

Concerned member states:

Austria Belgium Denmark Finland France Germany Greece Italy
Luxembourg Netherlands Norway Portugal Spain Sweden
United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

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

Summary of Product Characteristics