Spizobactin 1,500,000 IU / 250 mg chewable tablets for dogs

Authorised

- Metronidazole
- Spiramycin

Product identification

Medicine name:
Spizobactin 1,500,000 IU / 250 mg chewable tablets for dogs
SPIZOBACTIN 1.500.000 UI/250 mg comprimate masticabile pentru caini

Active substance:
Metronidazole

Spiramycin

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Metronidazole
250.00 milligram(s) / 1.00 Tablet

Spiramycin
357.14 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Chewable tablet

Withdrawal period by route of administration:
Oral use:

- **Dog**

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01RA04

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

Authorisation status:
Valid

Authorised in:
Romania

Package description:
(ID10) 100 Chewable tablets: cardboard box with 10 cardboard boxes each with 1 Blister (PolyVinyl Chloride, PolyEthylene, PolyVinylidene Chloride) with 10 Chewable tablets, closed with foil (Aluminium)
(ID3) 30 Chewable tablets: cardboard box with 3 Blisters (PolyVinyl Chloride, PolyEthylene, PolyVinylidene Chloride) each with 10 Chewable tablets, closed with foil (Aluminium)
(ID2) 20 Chewable tablets: cardboard box with 2 Blisters (PolyVinyl Chloride, PolyEthylene, PolyVinylidene Chloride) each with 10 Chewable tablets, closed with foil (Aluminium)
(ID1) 10 Chewable tablets: cardboard box with 1 Blister (PolyVinyl Chloride, PolyEthylene, PolyVinylidene Chloride) with 10 Chewable tablets, closed with foil (Aluminium)
(ID11) 100 Chewable tablets: cardboard box with 1 Blister (PolyVinyl Chloride, PolyEthylene, PolyVinylidene Chloride) with 10 Chewable tablets, closed with foil (Aluminium)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Le Vet. Beheer B.V.

Marketing authorisation date:
22/08/2017

Manufacturing sites for batch release:
Lelypharma B.V.

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

Authorisation number:
220143

Date of authorisation status change:
3/10/2024

Reference member state:
Germany

Procedure number:
DE/V/0171/002

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway 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

Combined File of all Documents

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

Source URL: *https://medicines.health.europa.eu/veterinary/600000062861*