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

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 tablet: Box (board) with 10 Box (board) each with 1 Blister (aluminium) with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID3) 30 Chewable tablet: Box (board) with 3 Blister (aluminium) each with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID2) 20 Chewable tablet: Box (board) with 2 Blister (aluminium) each with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID1) 10 Chewable tablet: Box (board) with 1 Blister (aluminium) with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID11) 100 Chewable tablet: Box (board) with 10 Blister (aluminium) each with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)

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.
Genera d.d.

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

Authorisation number:
220143

Date of authorisation status change:
27/10/2025

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

English (PDF)
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