Spizobactin 3,000,000 IU / 500 mg chewable tablets for dogs

Authorised

- Metronidazole
- Spiramycin

Product identification

Medicine name:
Spizobactin 3,000,000 IU / 500 mg chewable tablets for dogs

Active substance:
Metronidazole

Spiramycin

Target species:
Dog

Route of administration:
Oral use

Product details

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

Spiramycin

714.28 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:
Iceland

Package description:
(ID11) 100 Chewable tablet: Box (cardboard) with 10 Blister (aluminium) each with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID1) 10 Chewable tablet: Box (cardboard) with 1 Blister (aluminium) with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID2) 20 Chewable tablet: Box (cardboard) with 2 Blister (aluminium) each with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID3) 30 Chewable tablet: Box (cardboard) with 3 Blister (aluminium) each with 10 Chewable tablet, closed with Foil (polyvinyl chloride, polyethylene, polyvinylidene chloride)
(ID10) 100 Chewable tablet: Box (cardboard) with 10 Box (cardboard) each with 1 Blister (aluminium) 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:
4/08/2017

Manufacturing sites for batch release:
Lelypharma B.V.
Genera d.d.

Responsible authority:
Icelandic Medicines Agency

Authorisation number:
IS/2/17/010/03

Date of authorisation status change:
4/08/2017

Reference member state:
Germany

Procedure number:
DE/V/0171/003

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

Labelling

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

Package Leaflet

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

Summary of Product Characteristics

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

Combined File of all Documents

English (PDF)
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