

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:

Norway

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:

24/10/2017

Manufacturing sites for batch release:

Lelypharma B.V.

Genera d.d.

Responsible authority:

Norwegian Medical Products Agency

Authorisation number:

16-11313

Date of authorisation status change:

24/10/2017

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

Combined File of all Documents