SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spizobactin 750,000 IU / 125 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Spiramycin	750,000 IU
Metronidazole	125 mg

Excipients:

Qualitative composition of excipients and other constituents
Starch, pregelatinised
Cellulose, microcrystalline
Lactose monohydrate
Hydroxypropyl cellulose
Yeast (dried)
Chicken flavour
Silica, colloidal anhydrous
Magnesium stearate

Light brown with brown spots, round and convex chewable tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the adjunct treatment of mechanical or surgical periodontal therapy in the treatment of multi-bacterial infections of periodontal and related (peri)oral conditions e.g. stomatitis, gingivitis, glossitis, periodontitis, tonsillitis, dental fistula and other fistulous wounds in the oral cavity, cheilitis and sinusitis – in dogs caused by microorganisms susceptible to

spiramycin / metronidazole, such as Gram-positive bacteria and anaerobes (see also section 3.4 and 3.5).

3.3 Contraindications

Do not use in cases of hepatic disorders.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

In many cases of endodontic/periodontal disease the primary treatment is non-medicinal and does not require antimicrobial medication.
Antimicrobial treatment of periodontal disease should be accompanied or preceded by endodontic therapy and/or professional dental cleaning especially if the disease is advanced. Dog owners are encouraged to routinely brush their dog's teeth to remove plaque to prevent or to control periodontal disease.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The combination of spiramycin and metronidazole should not be used as first-line empirical treatment.
Whenever possible, metronidazole and spiramycin should only be used based on susceptibility testing of the pathogens.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Limiting the duration of treatment is necessary because damage to the germ cells cannot be excluded with the use of metronidazole, and because in long-term studies with high doses, an increase of certain tumours was seen in rodents. The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Metronidazole has confirmed mutagenic and genotoxic properties in laboratory animals as well as in humans. Metronidazole is a confirmed carcinogen in laboratory animals and has possible carcinogenic effects in humans. However, there is inadequate evidence in humans for the carcinogenicity of metronidazole.
Metronidazole may be harmful for the unborn child. Pregnant women should be careful when handling this veterinary medicinal product.
Spiramycin and metronidazole may in rare cases induce hypersensitivity reactions, e.g. contact dermatitis.
Direct contact with the skin or mucous membranes of the user should be avoided because of the risk of sensitization. People with known hypersensitivity to the active substances or to any of the excipients should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product to avoid skin contact and hand-to-mouth contact with the veterinary medicinal product.

Metronidazole may cause adverse (neurological) effects if ingested by a child. To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands thoroughly after handling the tablets.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Vomiting Hypersensitivity[a]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Haematuria Male reproductive tract disorder[b]

[a] In cases of hypersensitivity reactions, treatment should be stopped.
[b] Spermatogenesis disorder

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Spiramycin has not been found to be teratogenic or embryo- or foetotoxic. Studies in laboratory animals have shown inconsistent results with regard to teratogenic/embryotoxic effects of metronidazole. Metronidazole and spiramycin are excreted in milk.
The use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use concomitantly with bactericidal antibiotics.
Macrolides, such as e.g. spiramycin act antagonistic to penicillins and cephalosporins.
The veterinary medicinal product should not be used concurrently with other antibiotics of the macrolide group.
Metronidazole may have an inhibitory effect on the degradation of other drugs in the liver, such as phenytoin, cyclosporine and warfarin.
Phenobarbital may increase hepatic metabolism of metronidazole resulting in decreased serum concentration of metronidazole.

3.9 Administration routes and dosage

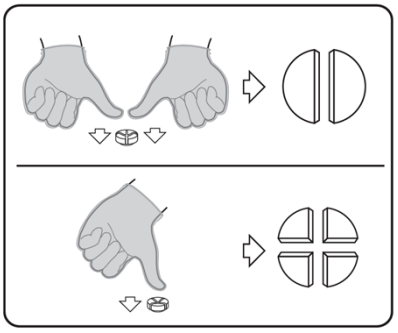
Oral use.

75 000 IU spiramycin + 12.5 mg metronidazole per kg body weight, in more severe cases 100 000 IU spiramycin + 16.7 mg metronidazole per kg body weight, administered daily for 6 - 10 days depending on the severity of the disease.
In severe cases one can start with the higher dose and go back in the course of treatment on to the lower dose.
The daily dose may be given once daily or divided equally for twice daily administration.
The treatment should always be continued for 1-2 days after resolution of symptoms in order to prevent relapses. The tablets are to be administered either deep in the mouth (on the base of the tongue) or given with a small amount of food containing the tablet, to ensure all the tablet is consumed.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The following table is intended as a guide to dispensing the veterinary medicinal product at approximately the standard dose rate of 75 000 IU spiramycin + 12.5 mg metronidazole per kg body weight.

Body weight	Spizobactin 750,000 IU / 125 mg for dogs	Spizobactin 1,500,000 IU / 250 mg for dogs	Spizobactin 3,000,000 IU / 500 mg for dogs
2.5 kg	¼		
5.0 kg	½	¼	
7.5 kg	¾		
10 kg	1	½	¼
12.5 kg	1 ¼		
15 kg	1 ½	¾	
17.5 kg	1 ¾		
20 kg	2	1	½
25 kg		1 ¼	
30 kg		1 ½	¾
35 kg		1 ¾	
40 kg		2	1
50 kg			1 ¼
60 kg			1 ½
70 kg			1 ¾
80 kg			2

¼ = ¼ Tablet ½ = ½ Tablet ¾ = ¾ Tablet 1 = 1 Tablet

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halves: press down with your thumbs on both sides of the tablet.

Quarters: press down with your thumb in the middle of the tablet

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

If neurological signs occur, treatment should be discontinued, and the patient should be treated symptomatically.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01RA04

4.2 Pharmacodynamics

Spiramycin is an antibiotic of the macrolide group. It acts markedly bacteriostatic by inhibition of protein synthesis (interfering with the translation reaction on the ribosome). Its spectrum of activity includes mainly Gram-positive bacteria. Three different mechanisms account for most bacterial resistance to the action of macrolides: (1) rRNA methylation; (2) active efflux; and (3) enzymatic inactivation. The first two mechanisms are the most frequent ones and genes coding for these mechanisms are often located on mobile elements. rRNA methylation, encoded by erythromycin-resistant methylase (erm) genes, results in cross-resistance to the macrolides, lincosamides, and streptogramin B (MLSB resistance).

Metronidazole is an imidazole derivative and acts against representatives of protozoa (flagellates and amoeba) and against Gram-positive and Gram-negative anaerobes.

The combination spiramycin and metronidazole broadens the spectrum due to the complementary antibacterial pattern of the two drugs. Synergistic effects have been demonstrated in some pathogens in in vitro studies and in experimental infections of laboratory animals.

4.3 Pharmacokinetics

After oral administration, peak plasma levels of spiramycin-I (main component of spiramycin) of 4.4 µg/ml are obtained within 1.3 hours. Spiramycin rapidly reaches high tissue levels that are 10-15 times higher than in plasma. The concentrations in the mucous membranes and saliva are particularly high. After a single oral dose of spiramycin concentrations remain present for about 30-40 hours.
Spiramycin is eliminated in the dog via the bile. The terminal half-life is about 8.6 hours.

After oral administration, peak plasma levels of metronidazole of 18 µg/ml are obtained within 1.4 hours. After oral ingestion metronidazole diffuses rapidly and completely in all body tissues. After 24 hours blood levels > 0.5 µg/ml are still detectable in most dogs. Excretion is via the urine. The terminal half-life is about 5.3 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life of divided tablets: 3 days.

5.3 Special precautions for storage

Do not store above 30 °C.

5.4 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister
Pack sizes:
Cardboard box of 1, 2, 3 or 10 blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 41821/4051

8. DATE OF FIRST AUTHORISATION

12 September 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall

Approved: 11 November 2025