1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxibactin 500 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Amoxicillin 500 mg
(equivalent to 575 mg amoxicillin trihydrate)

Excipients:

Qualitative composition of excipients and other constituents
Magnesium stearate
Silica, colloidal anhydrous
Sodium starch glycolate (Type A)
Yeast (dried)
Chicken flavour

White to off white with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into halves and quarters.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of primary and secondary infections of the airways, such as rhinitis caused by *Pasteurella* spp. and *Streptococcus* spp., and bronchopneumonia caused by *Pasteurella* spp., *Escherichia coli* and Gram-positive cocci.
Treatment of primary infections of the urogenital tract, such as pyelonephritis and infections of the lower urinary tract caused by *Escherichia coli, Proteus* spp. and Gram-positive cocci, endometritis caused by *Escherichia coli, Streptococcus canis* and *Proteus* spp., and vaginitis as a result of mixed infections.
Treatment of mastitis caused by Gram-positive cocci and *Escherichia coli*.
Treatment of local skin infections caused by *Streptococcus* spp.

3.3 Contraindications

Do not use in cases of hypersensitivity to penicillins or other substances of the β-lactam group or to any of the excipients.
Do not administer to gerbils, guinea pigs, hamsters, rabbits and chinchillas.
Do not use in animals with serious renal dysfunction accompanied by anuria or oliguria.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated and the use of the veterinary medicinal product based on a benefit-risk assessment by the veterinary surgeon.
Caution is advised in the use in small herbivores other than those which have been contraindicated in the section 3.3.
Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for amoxicillin, bacteriological sampling and susceptibility testing are recommended. Increased antimicrobial resistance are reported among *E. Coli* isolates including multidrug-resistant *E. Coli*. Special precautions should be taken when multi-drug resistance is suspected based on susceptibility testing. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other beta lactam antimicrobials or other classes of antimicrobials due to the potential for cross resistance.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
The 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:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
Wash hands after handling the tablets.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting[a], Diarrhoea[a] Hypersensitivity reaction (Allergic skin reaction, anaphylaxis)[b]

[a] Mild.

[b] In these cases, discontinue administration and give symptomatic therapy.

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action. The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The recommended dose is 10 mg amoxicillin per kg bodyweight, twice daily for a minimum of 5 consecutive days. The majority of routine cases respond after between 5 and 7 days of therapy. If no improvement is observed after 5 – 7 days, the diagnosis should be re-assessed. In chronic or refractory cases, a longer course of therapy may be required.

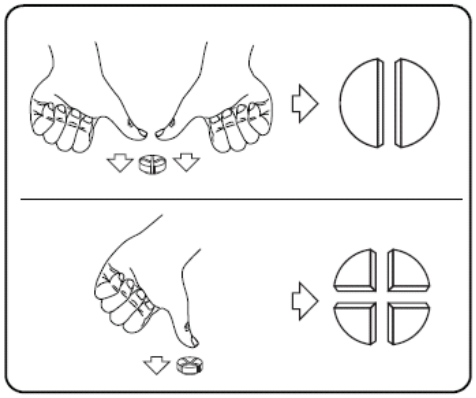
The following table is intended as a guide to dispensing the veterinary medicinal product at the standard dose rate of 10 mg per kg bodyweight twice daily.

	Number of tablets twice daily		
Body weight (kg)	**Amoxicillin 50 mg for dogs and cats**	**Amoxicillin 250 mg for dogs**	**Amoxicillin 500 mg for dogs**
1 – 1.25			
>1.25 – 2.5			
>2.5 – 3.75			
>3.75 – 5			
>5 – 6.25		or	
>6.25 – 12.5			or
>12.5 – 18.75			
>18.75 - 25			or 
>25 – 31.25			

>31.25 – 37.5		or
>37.5 - 50		or
>50 – 62.5		
>62.5 - 75		

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

Tablets can be divided into halves or quarters 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)

In case of overdose no other adverse reactions are known than those described in section 3.6.

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 : QJ01CA04

4.2 Pharmacodynamics

General Properties
Amoxicillin is a beta-lactam antibiotic, and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins. Beta-lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis of growing cells only. Beta-lactam antibiotics can be referred to as a time-dependent antibiotic.
Antimicrobial spectrum

Amoxicillin is a broad-spectrum antibiotic and generally active against some Gram-negative and most Gram-positive bacteria (Germ-vet 2007) e.g. penicillin sensitive *Pasteurella* spp., *Proteu*s spp, *Streptococcus* spp., *E. coli*, and Gram-positive cocci.
Resistance
Amoxicillin is acid-resistant but is not resistant to the action of beta-lactamases, which can hydrolyse the molecules causing the beta-lactam ring structure to open, causing inactivity of the antibiotic.
Most Gram-negative bacteria are intrinsically resistant to many beta-lactam drugs. This is partly due to the mechanism of action of the drug and the structure of the membrane of the bacteria.
Acquired resistance to beta-lactam drugs in clinical isolates may be due to beta-lactamase activity specified by plasmids or to mutational changes in chromosomal loci. In some strains a single step mutation may be responsible for resistance, whereas in others resistance may be due to several mutations.
Acquired resistance prevalence may be high in *E Coli*.

4.3 Pharmacokinetics

Amoxicillin is well absorbed after oral administration. In dogs, the systemic bioavailability is 60-70%.
Amoxicillin has a relatively small apparent distribution volume, low plasma-protein binding (34% in dogs) and a short elimination half-life period due to active tubular excretion by the kidneys.
After absorption, highest concentrations are found in the kidneys (urine) and bile, followed by the liver, lungs, heart and spleen.
Distribution of amoxicillin into cerebrospinal fluid is low unless the meninges are inflamed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life of the divided tablets: 4 days.

5.3 Special precautions for storage

Do not store above 30°C.
Any unused tablet portion should be returned to the open blister.

5.4 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 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 products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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(S)

VPA10475/013/003

8. DATE OF FIRST AUTHORISATION

16/01/2015

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

08/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).