SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxibactin 250 mg tablets for dogs (AT, BE, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK)
Amoxibactin vet 250 mg tablets for dogs (DK, FI, IS, NO, SE, EE, LT, LV, PL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:
Active substance:
Amoxicillin 250 mg (equivalent to 287.50 mg amoxicillin trihydrate)
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
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 equal halves and quarters.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in case 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.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated and the use of the product based on a risk/benefit evaluation by the veterinary surgeon.
Caution is advised in the use in small herbivores other than those in the section 4.3.
Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for amoxicillin, bacteriological sampling and susceptibility testing are recommended.
Whenever possible, the product should only be used based on susceptibility testing.
Use of the 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.
Official, national and regional antimicrobial policies should be taken into account when product is used.

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 product if you know you are sensitised, or if you have been advised not to
work with such preparations.
Handle this 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.

4.6 Adverse reactions (frequency and seriousness)

Mild gastrointestinal symptoms (diarrhoea and vomiting) may occur after administration of the product. Hypersensitivity reactions (allergic skin reactions, anaphylaxis) may occasionally occur. In these cases, administration should be discontinued and a symptomatic treatment given.

4.7 Use during pregnancy and/or lactation.

To date, laboratory studies in animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. However, as no studies have been carried out in pregnant or lactating dogs, it is recommended to use the product only according to the benefit/risk assessment by the responsible veterinarian.

4.8 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.

4.9 Amounts to be administered and administration route

For oral administration in dogs.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

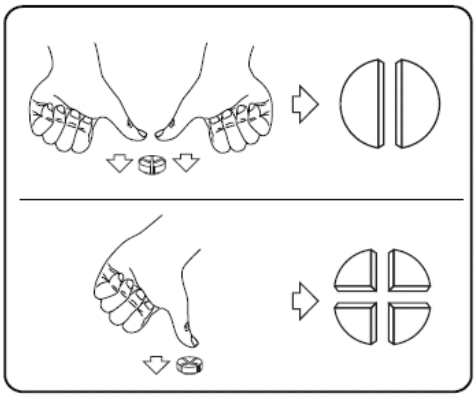
Dosage
The recommended dose is 10 mg amoxicillin per kg bodyweight, twice daily for a minimum of 5 consecutive days. The majority of routine cases respond after between 5 and 7 days of therapy. If no improvement is observed after 5 – 7 days, the diagnosis should be re-assessed. In chronic or refractory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

The following table is intended as a guide to dispensing the 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 equal 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.



Equal halves: press down with your thumbs on both sides of the tablet.
Equal quarters: press down with your thumb in the middle of the tablet.

4.10 Overdose (symptoms, emergency procedures, antidotes)

In case of overdose no other adverse reactions are known than those described in section 4.6.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use. Penicillins with extended spectrum.

ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

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., *Proteus* 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*.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Microcrystalline cellulose
Silica, colloidal anhydrous
Sodium starch glycolate
Yeast (dried)
Chicken flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4. Special precautions for storage

Do not store above 30°C.
Any unused tablet portion should be returned to the open blister and used within 4 days.

6.5 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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local/national requirements.

7. MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 41821/4015

9. DATE OF FIRST AUTHORISATION

December 2014

10. DATE OF REVISION OF THE TEXT

December 2014

APPROVED T. NASH **17/12/14**