Amoxibactin®

250 mg tablets for dogs

UK IE

Marketing authorisation holder: Le Vet Beheer BV, Wilgenweg 7, 3421 TV Oudewater, The Netherlands
Manufacturer responsible for batch release: LelyPharma BV, Zuiveringweg 42, 4283 PZ Lelystad, The Netherlands
Name of the veterinary medicinal product: Amoxibactin 250 mg tablets for dogs
Amoxicillin
Statement of the active substance and other ingredients:
1 tablet contains:
Active substance: Amoxicillin 250 mg (equivalent to 287.50 mg amoxicillin trihydrate)
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 or quarters.

Indications: 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 (inflammation of the mammary gland) caused by Gram-positive cocci and *Escherichia coli*. Treatment of local skin infections caused by *Streptococcus* spp.

Contraindications: Do not use in case of hypersensitivity to penicillins or other substances of the β-lactam group (i.e. cephalosporins) 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 (no or very low output of urine).

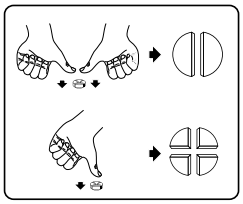
Adverse reactions: Mild gastrointestinal symptoms (diarrhoea and vomiting) may occur after administration of the product. Hypersensitivity reactions (allergic skin reactions, anaphylaxis) may occasionally occur. In these cases, administration should be discontinued and a symptomatic treatment given. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Target species: Dogs.

Dosage for each species, route and method of administration: 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 body weight, twice daily for a minimum of 5 consecutive days. The majority of routine cases respond 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 body weight twice daily.

Number of tablets twice daily			
Body weight (kg)	**Amoxibactin 50 mg for dogs and cats**	**Amoxibactin 250 mg for dogs**	**Amoxibactin 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



Advice on correct administration: 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.

Withdrawal period: Not applicable.

Special storage precautions: Keep out of the sight and reach of children.
Do not store above 30°C. Any unused tablet portion should be returned to the open blister and used within 4 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton or blister after 'EXP'.
The expiry date refers to the last day of that month.

Special warnings:
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 'Contraindications'. 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 this leaflet 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 the 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.
Use during pregnancy 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 and cats, it is recommended to use the product only according to the benefit/risk assessment by the responsible veterinarian.
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.
Overdose (symptoms, emergency procedures, antidotes): In case of overdose no other adverse reactions are known than those described in the section 'Adverse reactions'.

Special precautions for the disposal of unused product or waste materials: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: December 2014

Other information: For animal treatment only. To be supplied only on veterinary prescription.

UK: Vm 41821/4015 POM-V Prescription Only Medicine - Veterinarian

IE: VPA 10475/013/002 POM Prescription Only Medicine

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.
Veterinary medicinal product authorised for use in UK and IE.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Dechra Veterinary Products Limited,
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