

PARTICULARS TO APPEAR ON THE OUTER PACKAGE – CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxicibactin 50 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Amoxicillin 50 mg (equivalent to 57.50 mg amoxicillin trihydrate)

3. PACKAGE SIZE

10 tablets

20 tablets

30 tablets

40 tablets

50 tablets

60 tablets

70 tablets

80 tablets

90 tablets

100 tablets

250 tablets

500 tablets

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Divided tablets: use within 4 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Any unused tablet portion should be returned to the open blister.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/4014

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS - Alu/PVC/PE/PvDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxicibactin



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin 50 mg / tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Amoxicibactin 50 mg tablets for dogs and cats

2. Composition

Each tablet contains:

Active substance:

Amoxicillin 50 mg
(equivalent to 57.50 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 halves and quarters.

3. Target species

Dogs and cats.



4. Indications for use

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.

5. Contraindications

Do not use in cases 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).

6. Special warnings

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 'Contraindications'.

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 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.

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.

Pregnancy and lactation:

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

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:

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

7. Adverse events

Dogs and cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting ^a , Diarrhoea ^a Hypersensitivity reaction (Allergic skin reaction, anaphylaxis (severe allergic reaction)) ^b
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^a Mild.

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

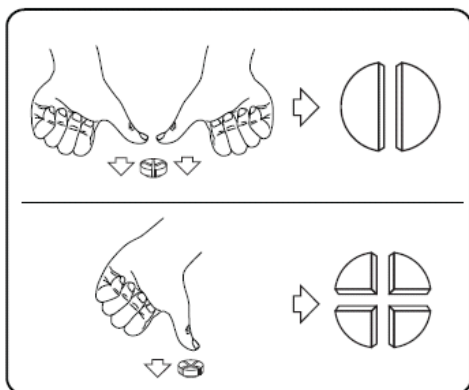
The following table is intended as a guide to dispensing the veterinary medicinal product at the standard dose rate of 10 mg per kg bodyweight twice daily.

Body weight (kg)	Number of tablets twice daily		
	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

9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable.

11. 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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

Shelf life of the divided tablets: 4 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41821/4014

Pack sizes:

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Lelypharma B.V.
Zuiveringweg 42
4283 PZ Lelystad
The Netherlands

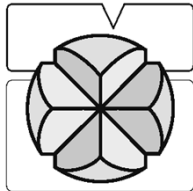
Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel.: +44 (0)1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V



Divisible tablet

Gavin Hall
Approved: 08 May 2026