

**ANNEX II**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

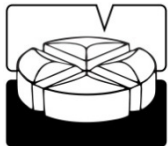
Amoxicibactin 50 mg tablets for dogs and cats / pictograms  
Amoxicillin

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 tablet contains:  
**Active substance:**  
Amoxicillin 50 mg (equivalent to 57.50 mg amoxicillin trihydrate)

**3. PHARMACEUTICAL FORM**

Tablet.



Divisible tablet

**4. 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

**5. TARGET SPECIES**

Dogs and cats

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

User warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. Read the package leaflet for full user warnings

**10. EXPIRY DATE**

EXP:

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.  
To be supplied only on veterinary prescription

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 41821/4014

**17. MANUFACTURER'S BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Alu/PVC/PE/PvDC blisters**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Amoxicibactin 50 mg tablets for dogs and cats  
Amoxicillin

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Le Vet. Beheer B.V.

**3. EXPIRY DATE**

EXP:

**4. BATCH NUMBER**

Lot.

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET FOR:

Amoxicillin 50 mg tablets for dogs and cats

### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxicillin 50 mg tablets for dogs and cats  
Amoxicillin

### 3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 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.

### 4. 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.

### 5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to penicillins or other substances of the  $\beta$ -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. ADVERSE REACTIONS**

Mild gastrointestinal symptoms (diarrhoea and vomiting) may occur very rarely (less than 1 animal in 10,000 animals treated, including isolated reports) after administration of the product.

Hypersensitivity reactions (allergic skin reactions, anaphylaxis) may occur very rarely. In these cases, administration should be discontinued and a symptomatic treatment given.

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

## **7. TARGET SPECIES**

Dogs and cats

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

For oral administration in dogs and cats.

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.

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  
Tablet

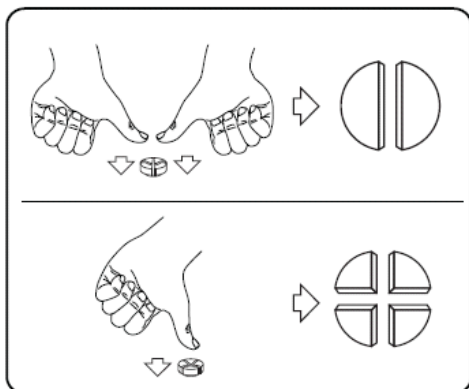
◐ = ½ Tablet

◑ = ¾ Tablet

⊕ = 1

## 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 PERIOD**

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 and used within 4 days.

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

## **12. 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 which have been contraindicated in the section 5 '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 are suspected based on susceptibility testing.

Whenever possible, the product should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in the 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 product is used.

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 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.

### **Pregnancy and lactation**

The safety of the 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 in accordance with 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 section 6 'Adverse reactions'.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater or household waste. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

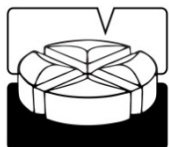
June 2020

## **15. OTHER INFORMATION**

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



**Divisible tablet**

Approved 03 July 2020

