ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

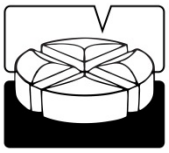
Amoxibactin 500 mg tablets for dogs / pictogram
Amoxicillin

2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet contains:
Active substance:
Amoxicillin 500 mg (equivalent to 575 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

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 41821/4016

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

Amoxibactin 500 mg tablets for dogs
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:

Amoxibactin 500 mg tablets for dogs

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

Amoxibactin 500 mg tablets for dogs
Amoxicillin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 tablet contains:
Active substance:

Amoxicillin 500 mg (equivalent to 575 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 *Escherichi 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 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. 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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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.

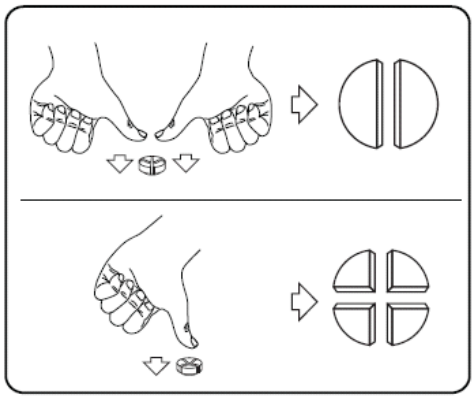
The following table is intended as a guide to dispensing the product at the standard dose rate of 10 mg per kg bodyweight twice daily.

	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	¼		
>1.25 – 2.5	½		
>2.5 – 3.75	¾		
>3.75 – 5	1		
>5 – 6.25	1 ¼	or ¼	
>6.25 – 12.5		½	or ¼
>12.5 – 18.75		¾	
>18.75 - 25		1	or ½
>25 – 31.25		1 ¼	
>31.25 – 37.5		1 ½	or ¾
>37.5 - 50		2	or 1
>50 – 62.5			1 ¼
>62.5 - 75			1 ½

¼ = ¼ Tablet ½ = ½ Tablet ¾ = ¾ Tablet 1 = 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 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 'Contra indications'.
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. 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.

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

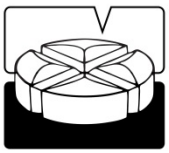
Medicines should not be disposed of via wastewater or household waste. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

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: 30 June 2020