ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabactin 1000 mg tablets for dogs
cefalexin

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: 1000 mg of cefalexin

3. PHARMACEUTICAL FORM

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

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP:
Shelf life of divided tablets: 4 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL 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 41821/4036

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium-PVC/PE/PVDC **blisters**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabactin 1000 mg tablets
cefalexin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Cefabactin 1000 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.
Zuiveringsweg 42, 8243 PZ Lelystad, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabactin 1000 mg tablets for dogs
cefalexin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:

Active substance:
Cefalexin (as cefalexin monohydrate) 1000 mg

Light brown with brown spots, round and convex, flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

4. INDICATIONS

For the treatment:
- Respiratory tract infections, especially bronchopneumonia, caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli* and *Klebsiella* spp.
- Urinary tract infections caused by *Escherichia coli*, *Proteus* spp. and *Staphylococcus* spp.
- Skin infections caused by *Staphylococcus* spp.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance, to other cephalosporins, to other substances of the β-lactam group or to any of the excipients.
Do not use in known cases of resistance to cephalosporins or penicillins.
Do not use in rabbits, guinea pigs, hamsters and gerbils.

6. ADVERSE REACTIONS

Vomiting has been observed occasionally in dogs treated with products containing cefalexin. As with other antibiotics, diarrhoea can occur. In case of recurring vomiting and/or diarrhoea, the treatment should be discontinued and the advice of the attending veterinarian sought. Lethargy can occur very rarely.
Hypersensitivity can occur rarely. In cases of hypersensitivity reactions the treatment should be discontinued."

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 AND METHOD OF ADMINISTRATION

For oral administration.
The recommended dose is 15-30 mg cefalexin per kg body weight twice a day, during at least 5 consecutive days. An extended course of treatment may be prescribed by the responsible veterinarian in cases of, for example, urinary tract infections or bacterial dermatitis.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

The following table is intended as a guide to dispensing the product at a dose rate of 15 mg cefalexine per kg bodyweight twice a day.

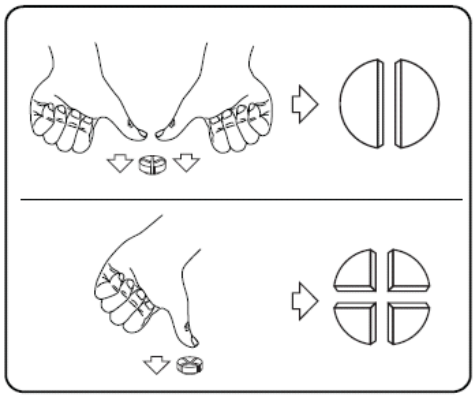
ADMINISTRATION TWICE DAILY

Body weight	Dose mg	Cefabactin 50 mg	Cefabactin 250 mg	Cefabactin 500 mg	Cefabactin 1000 mg
>0.5 kg – 0.8 kg	12.5		-	-	-
>0.8 kg – 1.6 kg	25		-	-	-
>1.6 kg – 2.5 kg	37.5		-	-	-
>2.5 kg – 3.3 kg	50		-	-	-
>3.3 kg – 5 kg	75		-	-	-
>5 kg – 6.6 kg	100		-	-	-
>6.6 kg – 8 kg	125			-	-
>8 kg – 10 kg	150		-	-	-
>10 kg – 12.5 kg	188	-		-	-
>12.5 kg – 16.6 kg	250	-			-
>16.6 kg – 20 kg	313				
>20 kg – 25 kg	375	-		-	-
>25 kg – 29 kg	438	-		-	-
>29 kg – 33 kg	500	-			
>33 kg – 41 kg	625	-	-		-
>41 kg – 50 kg	750	-	-		
>50 kg – 58 kg	875	-	-		-
>58 kg – 66 kg	1000	-	-		
>66 kg – 83kg	1250	-	-	-	

 = ¼ Tablet  = ½ Tablet  = ¾ Tablet  = 1 Tablet

9. ADVICE ON CORRECT ADMINISTRATION

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface with its scored side facing up.



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.
Shelf life of divided tablets after first opening the immediate packaging: 4 days.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the package after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special precautions for use in animals

Due to the likely variability (time, geographical) in the occurrence of cefalexin resistant bacteria, bacteriological sampling and susceptibility testing are recommended.
The product should only be used based on susceptibility testing of the bacteria isolated from the animals. If this is not possible, therapy should be based on local epidemiological information.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the product deviating from the instructions given in this package leaflet may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness of treatment with other beta-lactam antibiotics due to the potential for cross-resistance.
In case of chronic renal insufficiency the dose should be reduced or the dosage interval should be increased. 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 penicillin may lead to cross-reactions to cephalosporin 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 be in contact with such substances.

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.

To avoid accidental ingestion of the product by a child, divided or unused tablets should be returned to the open blister pocket and placed back in the outer carton.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation

Laboratory studies in rats and mice have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product in dogs has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction

In order to ensure efficacy, the veterinary medicinal product should not be used in combination with bacteriostatic antibiotics (macrolides, sulfonamides and tetracyclines).
Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.

Overdose (symptoms, emergency procedures, antidotes)

No other known side effects than those under section ‘Adverse reactions’.
In the event of overdose, treatment should be symptomatic

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

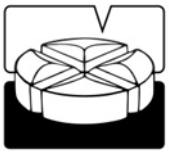
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. OTHER INFORMATION

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 25 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: 27/10/21