ANNEX III

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Cefalexin (as cefalexin monohydrate) 1000 mg

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

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Use divided tablets within 4 days.

9. SPECIAL STORAGE PRECAUTIONS

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 41821/3012

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium-PVC/PE/PVDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabactin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1000 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Use divided tablets within 4 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

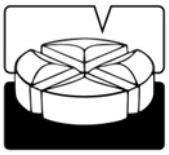
Cefabactin 1000 mg tablets for dogs

2. Composition

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.



3. Target species

Dogs.

4. Indications for use

For the treatment of:
- 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 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. Special warnings

Special precautions for safe use in the target species:
Due to the likely variability (time, geographical) in the occurrence of cefalexin resistant bacteria, bacteriological sampling and susceptibility testing are recommended.

The veterinary medicinal 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.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Use of the veterinary medicinal 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 veterinary medicinal 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 effects harmful to the foetus.
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.

Interaction 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 (suppressing bacterial growth) antibiotics (macrolides, sulfonamides and tetracyclines).
Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance the risks of kidney damage.

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

<Special restrictions for use and special conditions for use:>

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction (allergic reaction)[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting [b], Diarrhoea [b], Lethargy

[a] The treatment should be discontinued.
[b] In case of recurrence, the treatment should be discontinued and the advice of the attending veterinarian sought.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

For oral use.
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 skin inflammations caused by bacteria.
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 veterinary medicinal product at a dose rate of 15 mg cefalexine per kg body weight twice a day.

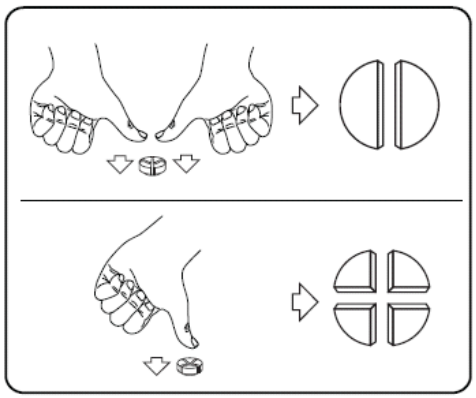
ADMINISTRATION TWICE DAILY

Body weight	Dose mg	Cefabactin 50 mg	Cefabactin 250 mg	Cefabactin 500 mg	Cefabactin 1000 mg
>0.5 kg – 0.8 kg	12.5	¼	-	-	-
>0.8 kg – 1.6 kg	25	½	-	-	-
>1.6 kg – 2.5 kg	37.5	¾	-	-	-
>2.5 kg – 3.3 kg	50	1	-	-	-
>3.3 kg – 5 kg	75	1 ½	-	-	-
>5 kg – 6.6 kg	100	2	-	-	-
>6.6 kg – 8 kg	125	2 ½	½	-	-
>8 kg – 10 kg	150	3	-	-	-
>10 kg – 12.5 kg	188	-	¾	-	-
>12.5 kg – 16.6 kg	250	-	1	½	-
>16.6 kg – 20 kg	313		1 ¼		
>20 kg – 25 kg	375	-	1 ½	-	-
>25 kg – 29 kg	438	-	1 ¾	-	-
>29 kg – 33 kg	500	-	2	1	½
>33 kg – 41 kg	625	-	-	1 ¼	-
>41 kg – 50 kg	750	-	-	1 ½	¾
>50 kg – 58 kg	875	-	-	1 ¾	-
>58 kg – 66 kg	1000	-	-	2	1
>66 kg – 83kg	1250	-	-	-	1 ¼

¼ = ¼ Tablet ½ = ½ Tablet ¾ = ¾ Tablet 1 = 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.
This veterinary medicinal product does not require any special storage conditions.
Shelf life of divided tablets: 4 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp.
The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
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 41821/3012

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.

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 <and contact details to report suspected adverse reactions>:

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

<Local representatives <and contact details to report suspected adverse reactions>:>

<17. Other information>

Gavin Hall

Approved: 05 December 2024