SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabactin 1000 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Cefalexin (as cefalexin monohydrate) 1000 mg

Excipient(s):
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
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. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 the SPC 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.

4.6 Adverse reactions (frequency and seriousness)

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)

4.7 Use during 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.

4.8 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 antibiotics (macrolides, sulfonamides and tetracyclines). Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.

4.9 Amounts to be administered and administration route

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.

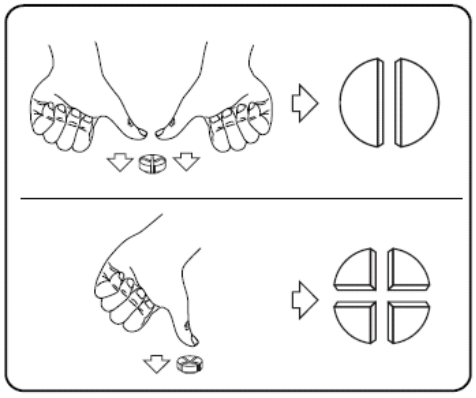
The following table is intended as a guide to dispensing the product at a dose rate of 15 mg cefalexine per kg body weight twice a day.

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		-	-	-
>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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No other known side effects than those under section 4.6.
In the event of overdose, treatment should be symptomatic.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use, first-generation cephalosporins
ATCvet Code: QJ01DB01

5.1 Pharmacodynamic properties

The mechanism of action of cephalosporins resembles that of the penicillins, in particular that of ampicillin (common beta-lactam ring). Cephalosporins especially has a time-dependent bactericidal effect in dividing bacteria. They bind irreversibly with 'penicillin-binding proteins (PBPs'), enzymes that are needed for the cross-coupling of peptidoglycan strands during the synthesis of the bacterial cell wall. This interferes with the cross-linkage of peptidoglycan chains necessary for bacterial cell strength and rigidity, and results in abnormal cell growth and cell lysis.
Cephalexin is active against both gram positive and some gram negative bacteria.

The following CLSI cephalothin veterinary breakpoints are available for dogs (CLSI VET01S ed. 5, November 2020). Cephalothin can be used as indicator of first generation cephalosporins.
Skin and soft tissue infections:
Skin and soft tissue infections:

Bacterial species	Susceptible	Resistant
Staphylococcus aureus and *Staphylococcus pseudintermedius*	≤ 2 µg/ml	≥ 4 µg/ml
Streptococcus spp and E. coli	≤ 2 µg/ml	≥ 8 µg/ml

Urinary tract infections:

Bacterial species	Susceptible	Resistant
E. coli, Klebsiella pneumoniae and *Proteus mirabilis*	≤ 16 µg/ml	≥ 32 µg/ml

As with penicillins resistance to cefalexin may be due to one of the following mechanisms of resistance: the production of various beta-lactamases, encoded on plasmids or not encoded or by multistage mutations. In the first case, there is almost always cross-resistance with ampicillin; in the other cases there is partial or complete cross-resistance to all penicillins and cephalosporins. Conversely, methicillin-resistant staphylococci are unsusceptible to cephalosporins.

5.2 Pharmacokinetic particulars

After administration of cephalexin monohydrate cephalexin rapidly and almost completely absorbed in the gastrointestinal tract. Absorption is delayed by food (lower blood levels). Protein plasma binding is approximately 20%.
Single oral administration of 20 mg of cephalexin per kg body weight to dogs resulted in a Tmax of approximately 1-1.5 hours, a Cmax in plasma of about 15 µg/ml and an elimination half-life of about 2 hours (bioavailability = 75% -80%). The volume of distribution is 1.62 l/kg.
After absorption, cephalexin is well distributed in the extracellular fluids of the body, however, the passage of biological membranes is limited. The concentrations of cephalexin are highest in the kidneys (urine), and bile, followed by the liver, lungs, heart, skeletal muscle and spleen.
Hardly any metabolism occurs in the liver. Elimination is almost entirely via the kidneys by tubular excretion and glomerular filtration. Cephalexin is also excreted in the bile in a concentration that is equal or somewhat higher than in the blood.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Potato Starch
Silica, colloidal hydrated
Yeast (dried)
Chicken Flavour
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life of divided tablets after first opening the immediate packaging: 4 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister.
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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 41821/4036

9. DATE OF FIRST AUTHORISATION

22 September 2016

10. DATE OF REVISION OF THE TEXT

October 2021

Approved: 27/10/21