Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare Flavour 1000 mg Tablets for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Cefalexin (as cefalexin monohydrate) 1000 mg

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.
Brown speckled oblong tablet, with one side flat and other side spherical with break mark on both sides.

The tablets can be divided into halves.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of infections of the respiratory tract, gastro-intestinal tract, urogenital tract, the skin and localised infections in soft tissue.

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, gerbils, guinea pigs and hamsters.

4.4 Special warnings for each target species

Cross resistance has been shown between cephalosporins and penicillins. Use of cefalexin should be carefully considered when susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.

4.5 Special precautions for use

Special precautions for use in animals

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s) isolated from the animal. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local / regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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.

As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced, antimicrobials known to be nephrotoxic should not be administered concurrently and the product should be used only according to a risk/benefit assessment by the responsible veterinarian.

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 product if you know you are sensitised or if you have been advised not to be in contact with such substances.

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 immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the outer packaging. 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 when given 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 should be sought.
In rare cases hypersensitivity can occur. In cases of hypersensitivity reactions, the treatment should be discontinued and occurring symptoms should be treated symptomatically.

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, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

The bactericidal activity of cephalosporins is reduced by concomitant administration of bacteriostatic acting compounds (macrolides, sulphonamides and tetracyclines).
Nephrotoxicity can be increased when 1st generation cephalosporins are combined with polypeptide antibiotics, aminoglycosides and some diuretics (furosemide).
Concomitant use with such active substances should be avoided.

4.9 Amounts to be administered and administration route

Oral use. A dose of 15 mg/kg twice daily is recommended, to be doubled where appropriate.

The product has a break mark on both sides. To enable more accurate dosing, half tablets may be used as necessary.

Treatment for five days is recommended. Any increase in dose or duration of use should be according to a risk/benefit assessment by the prescribing veterinarian (e.g. in cases of chronic pyoderma).

Tablets may be added to food if necessary.

To avoid under dosing, the bodyweight should be accurately determined.

The use of cefalexin tablets of lower strengths is advised for dogs with lower bodyweights.

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

The administration of cefalexin has been shown to produce no serious side-effects when administered at overdose.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, other beta-lactam antibacterials, first-generation cephalosporins.
ATCvet code: QJ01DB01.

5.1 Pharmacodynamic properties

Cefalexin is a semi-synthetic bactericidal antibiotic belonging to the cephalosporin group.
This bactericidal activity is mediated by drug binding to bacterial enzymes known as penicillin binding proteins (PBPs). Such enzymes are located on the inner membrane of the cell wall and their transpeptidase activity is required for the terminal stages of assembling this essential structure of the bacterial cell. Inactivation of PBPs interferes with the cross-linkage of peptidoglycan chains necessary for bacterial cell wall strength and rigidity. The bactericidal effect of cefalexin is mainly time dependent.

Cefalexin is active against a wide range of Gram-positive and Gram-negative bacteria. The following micro-organisms have been shown to be sensitive to cefalexin *in vitro: Staphylococcus* spp (including penicillin-resistant strains), *Streptococcus* spp, *Corynebacterium* spp, *Pasteurella multocida*, *Escherichia coli*, *Micrococcus* spp, *Moraxella* spp.

Cefalexin is resistant to the action of staphylococcal penicillinase and is therefore active against the strains of *Staphylococcus aureus* that are insensitive to penicillin (or related antibiotics such as ampicillin or amoxycillin) because of production of penicillinase.
Cefalexin is also active against the majority of ampicillin-resistant *E.coli*.

Resistance to cefalexin can be due to one of the following mechanisms of resistance. Firstly, the production of cephalosporinases, that inactivate the antibiotic by hydrolysis of the β-lactam ring, is the most prevalent mechanism among Gram-negative bacteria. This resistance is transmitted by plasmid or chromosomally. Secondly, a decreased affinity of the PBPs (penicillin-binding proteins) for beta-lactam drugs is frequently involved for beta-lactam resistant Gram-positive bacteria. Lastly, efflux pumps, extruding the antibiotic from the bacterial cell, and structural changes in porins, reducing passive diffusion of the drug through the cell wall, may contribute to improve the resistant phenotype of a bacterium.

Well-known cross-resistance (involving the same resistance mechanism) exists between antibiotics belonging to the beta-lactam group due to structural similarities. It occurs with beta-lactamases enzymes, structural changes in porins or variations in efflux pumps. Co-resistance (different resistance mechanisms involved) has been described in *E. coli* due to a plasmid harbouring various resistance genes.
Pseudomonas aeruginosa is known for resistance to cefalexin.

5.2 Pharmacokinetic particulars

Following oral administration, cefalexin is rapidly and almost completely absorbed. Peak plasma concentrations in the dog (C_{max}= 17.49 µg/ml) are achieved within approximately 1.5 hours (T_{max}= 1.55). Cefalexin is excreted in the urine in high concentrations and has an elimination half life ($T_{1/2}$) of approximately 2.5–3 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Potato starch
Magnesium stearate
Beef flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Return any ½ tablet to the blister pack and use within 48 hours.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Keep the blister in the outer carton.

6.5 Nature and composition of immediate packaging

The product is supplied in PVC/PE/PVDC/Aluminum foil blister packs each containing 10 tablets, in cardboard boxes containing 20, 100 or 250 tablets.

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-I
8020 Oostkamp
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10491/005/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 March 2017
Date of last renewal: 07 January 2022

10 DATE OF REVISION OF THE TEXT

January 2022