SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare flavour 500 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
500 mg cefalexin as cefalexin monohydrate.

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

3. PHARMACEUTICAL FORM

Tablets
Beige, flat tablets with a break mark on one side.

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 caused by bacteria sensitive to cefalexin.

4.3 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 rabbits, gerbils, guinea pigs and hamsters.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

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 penicillins, due to the potential for cross resistance.

In the case of an allergic reaction, treatment should be withdrawn.

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.

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 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.

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.

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been demonstrated in studies in pregnant or lactating dogs. Use only in accordance with a risk/benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

See section 4.5i Special precautions for use in animals.

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

For oral administration. A dose of 15 mg/kg twice daily is recommended, to be doubled where appropriate.

Cephacare flavour 500 mg tablets have a break mark on one side. 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 underdosing, 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 at many times the recommended dose rate.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL 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 which acts by interference with bacterial cell wall formation.

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.*

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 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 24 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

Cephacare flavour 500 mg tablets are supplied in PVC/aluminium 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 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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER

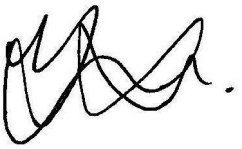
Vm 32742/4030

9. DATE OF FIRST AUTHORISATION

19 December 2008

10. DATE OF REVISION OF THE TEXT

August 2022



Approved: 11 August 2022