

Cephacare Flavour 50mg, 250mg and 500mg Tablets

Introduction



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Presentation

Cephacare Flavour 50mg

Beef flavoured, beige, round biconvex tablets with a break mark on one side. Each tablet contains 50mg cefalexin (as monohydrate). Indicated for cats and dogs.

Cephacare Flavour 250mg

Beef flavoured, beige, flat tablets with a break mark on one side. Each tablet contains 250mg cefalexin (as monohydrate). Indicated for dogs.

Cephacare Flavour 500mg

Beef flavoured, beige, flat tablets with a break mark on one side. Each tablet contains 500mg cefalexin (as monohydrate). Indicated for dogs.

Uses

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*.

Indications in dogs

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.

Indications in cats

Treatment of infections of the respiratory tract, urogenital tract, the skin and localised infections in soft tissue caused by bacteria sensitive to cefalexin.

Dosage and administration

For oral administration. Cephacare flavour tablets have a break mark on one side. To enable more accurate dosing, half tablets may be used as necessary. Tablets may also be added to food if necessary.

To avoid underdosing, the bodyweight should be accurately determined.

Dogs

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

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).

Cats

A dose of 15 mg/kg twice daily for 5 days is recommended.

Contra-indications, warnings, etc

For animal treatment only. 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.

The administration of cefalexin has been shown to produce no serious side-effects at many times the recommended dose rate.

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

Transient episodes of soft faeces and vomiting have been observed in cats when given products containing cefalexin. Treatment should be discontinued if vomiting and diarrhoea develop.

Vomiting has been observed occasionally in dogs when given products containing cefalexin.

Contraindications

Do not use in cases of known hypersensitivity to the active substance to other cephalosporins, to other substances of the b-lactam group or to any of the excipients.

Do not use in rabbits, gerbils, guinea pigs and hamsters.

User warnings

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.

Pharmaceutical precautions

Return any ½ tablet to the blister pack and use within 24 hours. Keep the blister pack in the outer carton. Keep out of the reach and sight of children. Do not store above 25°C.

Store in a dry place. Do not use after the expiry date stated on blister and carton.

Disposal

Any unused product or waste materials should be disposed of in accordance with national requirements.

Legal category

POM-V

Packaging Quantities

Cephacare Flavour 50mg are supplied in boxes of 100 tablets (10 blisters of 10 tablets). Cephacare Flavour 250mg and 500mg are supplied in boxes of 100 and 250 tablets (10 and 25 blisters of 10 tablets).

Further information

Following oral administration, cefalexin is rapidly and almost completely absorbed. Peak plasma concentrations (C_{max}= 14.38 µg/ml) are achieved within approximately 2 hours (T_{max}= 2.1 hours) in the cat. Peak plasma concentrations in the dog (C_{max}= 17.49 µg/ml) are achieved within approximately 1.5 hours (T_{max}= 1.55). In both species, cefalexin is excreted in the urine in high concentrations and has an elimination half life (T_{1/2}) of approximately 2.5 – 3 hours.

Marketing authorisation number

Cephacare Flavour 50mg: Vm 10347/4025

Cephacare Flavour 250mg: Vm 10347/4026

Cephacare Flavour 500mg: Vm 10347/4027

Significant Changes

GTIN (Global Trade Item No)

100 x 50mg Tablets:

05055037401165

100 x 250mg Tablets:

05055037401189

250 x 250mg Tablets:

05055037401196
100 x 500mg Tablets:
05055037401202
250 x 500mg Tablets:
05055037401219