

cephacare[®]

flavour 250mg

Tablets for Dogs

Each tablet contains:

Active substance: 250mg cefalexin as cefalexin monohydrate
Beef flavoured, beige, flat tablets with a break mark on one side.

Indications

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

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.

Adverse reactions

Vomiting has been observed occasionally in dogs when given products containing cefalexin. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Dosage and Administration

For oral administration.

A dose of 15mg/kg twice daily is recommended, to be doubled where appropriate.
Cephacare flavour 250mg tablets have a break mark on one side. To enable more accurate dosing, half tablets may be used as necessary.
Treatment for 5 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.

Special storage precautions

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

Store in a dry place. Do not use this veterinary medicinal product after the expiry date which is printed on the blister and carton after "Exp". The expiry date refers to the last day of the month.

Special warnings

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In the case of an allergic reaction, treatment should be withdrawn.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

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.

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 cephalosporins 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.

Disposal

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

Other information

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*.

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.

Package Quantities: Cephacare flavour 250mg tablets are supplied in packs of 100 and 250 tablets. Not all pack sizes may be marketed.

Marketing authorisation holder:

Animalcare Ltd, 10 Great North Way, York YO26 6RB, UK

Manufacturers responsible for batch release: Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, The Netherlands

Produlab Pharma B.V., Forellenweg 16, 4941 SJ, Raamsdonksveer, The Netherlands

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Veterinary medicinal product authorised in Ireland and the UK.

UK

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POM-V

To be supplied only on veterinary prescription

IE

VPA 10778/2/2

POM

Prescription Only Medicine