PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare flavour 50 mg tablets for cats and dogs.
Cefalexin as cefalexin monohydrate.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 50 mg cefalexin as cefalexin monohydrate.
Beef flavoured, beige, round biconvex tablets

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

20 tablets
100 tablets
250 tablets

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

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

Cats:
A dose of 15 mg/kg twice daily is recommended.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for user warnings and disposal advice. Penicillins and cephalosporins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

EXP: DD/MM/YY

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See package leaflet for user warnings and disposal advice.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 32742/4029

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare flavour 50 mg tablets for cats and dogs

50 mg cefalexin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

3. EXPIRY DATE

EXP: DD/MM/YY

4. BATCH NUMBER

BN

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Cephacare flavour 50 mg tablets for cats and dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare flavour 50 mg tablets for cats and dogs.
Cefalexin as cefalexin monohydrate.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)

Each tablet contains:
Active substance**:**
50 mg cefalexin as cefalexin monohydrate.
Beef flavoured, beige, round biconvex tablets

4. 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.

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.

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats and dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Tablets may be added to food if necessary.

To avoid underdosing, the bodyweight should be accurately determined.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

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.

12. 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 and cats. 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 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. 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.

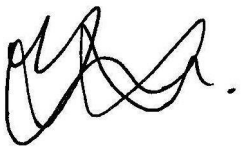
Cefalexin is also active against the majority of ampicillin-resistant *E.coli.*

Following oral administration, cefalexin is rapidly and almost completely absorbed. Peak plasma concentrations (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.

Cephacare flavour 50 mg tablets are supplied in packs of 20, 100 and 250 tablets.

Not all pack sizes may be marketed.

Prescription Only Medicine



Approved: 11 August 2022