1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare flavour 500 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Cefalexin (as cefalexin monohydrate) 500 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Potato starch
Magnesium stearate
Beef flavour

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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.

3.3 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 rabbits, gerbils, guinea pigs and hamsters.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in target species:

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

Use of the veterinary medicinal 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In the case of an allergic reaction, treatment should be withdrawn.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 veterinary medicinal product should be used only according to the benefit-risk 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.
People with known hypersensitivity to cefalexin should avoid contact with the veterinary medicinal product.
Handle this veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity*
Undetermined frequency (cannot be estimated from the available data):	Diarrhoea**, vomiting**

*When observed, the treatment should be discontinued and occurring symptoms should be treated symptomatically.
**When observed, treatment should be stopped and the advice of the attending veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

Oral use.

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

The veterinary medicinal product has 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 the benefit-risk assessment by the responsible veterinarian (e.g. in cases of chronic pyoderma).

Tablets may be added to food if necessary.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

To be completed in accordance with national requirements after the conclusion of the DCP.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DB01.

4.2 Pharmacodynamics

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.*

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Return any ½ tablet to the blister and use within 24 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER(S)

To be completed in accordance with national requirements and after conclusion of the DCP.

8. DATE OF FIRST AUTHORISATION

To be completed in accordance with national requirements and after conclusion of the DCP.

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare flavour 500 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 500 mg cefalexin as cefalexin monohydrate.

3. PACKAGE SIZE

20 tablets
100 tablets
250 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Return any ½ tablet to the blister and use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBERS

To be completed in accordance with national requirements and after conclusion of the DCP.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephacare flavour 500 mg tablets for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains 500 mg cefalexin.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cephacare flavour 500 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Cefalexin (as cefalexin monohydrate) 500 mg

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

3. Target species

Dogs.

4. Indications for use

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.

5. 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 rabbits, gerbils, guinea pigs and hamsters.

6. Special warnings

Special precautions for safe use in target species:

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

Use of the veterinary medicinal 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 veterinary medicinal product should be used only according to the benefit-risk 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.

- People with known hypersensitivity to cefalexin should avoid contact with the veterinary medicinal product.
- Handle this veterinary medicinal 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.

Pregnancy and lactation:

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.

Interaction with other medicinal products and other forms of interaction:

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.

Overdose:

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

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity*
Undetermined frequency (cannot be estimated from the available data):	Diarrhoea**, vomiting**

*When observed, the treatment should be discontinued and occurring symptoms should be treated symptomatically.
**When observed, treatment should be stopped and the advice of the attending veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: To be completed in accordance with national requirements and after conclusion of the DCP.

8. Dosage for each species, routes and method of administration

Oral use.

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

9. Advice on correct administration

The veterinary medicinal product has 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 the benefit-risk assessment by the responsible veterinarian (e.g. in cases of chronic pyoderma).

Tablets may be added to food if necessary.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Return any ½ tablet to the blister and use within 24 hours.
Keep the blister in the outer carton.
Do not store above 25 °C.
Store in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

The veterinary medicinal product is supplied in packs of 20, 100 or 250 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

Local representatives and contact details to report suspected adverse events:

To be completed in accordance with national requirements and after conclusion of the DCP.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information