SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kefavet vet 250 mg film-coated tablets for dogs
Kefavet vet 500 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Kefavet vet 250 mg film-coated tablets
Cefalexin monohydrate equivalent to 250 mg cefalexin

Kefavet vet 500 mg film-coated tablets
Cefalexin monohydrate equivalent to 500 mg cefalexin

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Macrogol	
Magnesium stearate	
Sodium starch glycolate (type A)	
Povidone	
Lactose monohydrate	
Saccharin sodium	
Peppermint oil	
Titanium dioxide (E171)	Kefavet vet 250 mg film-coated tablets: 0.550 mg Kefavet vet 500 mg film-coated tablets: 1.10 mg
Talc	
Hypromellose	

250 mg: White to yellowish, round (diameter approx. 10 mm), biconvex tablet scored on one side, "CX" above the score, "250" below the score.

500 mg: White to yellowish, oblong (size approx. 7 x 18 mm), biconvex tablet scored on both sides.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

Treatment of urinary tract infections and recurring severe dermatological infections caused by bacteria sensitive to cefalexin.

3.3 Contraindications

Do not use in cases of hypersensitivity to the cephalosporins or penicillin or to any of the excipients.

Do not use in case of resistance to the cephalosporins or penicillins occur.
Do not use in rabbits, guinea pigs, hamsters and gerbils.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In cases of known renal insufficiency, the dose must be reduced. Use of the veterinary medicinal product should be based on susceptibility testing and it should take into account official and local antimicrobial policies.
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiviness of treatment with other beta-lactam antibiotics, due to the potential for cross resistance.

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 veterinary medicinal product if you know you are sensitised or if you have been advised not to be in contact with such substances.

Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions. Wash hands after use.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty breathing, are more serious symptoms and require urgent medical attention.

In case of accidental ingestion, especially by a small child, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data):	Diarrhoea*, vomiting*

*Most often mild. In the event of severe gastrointestinal side effects, treatment should be discontinued.

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 also 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 and 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

Due to undesirable pharmacodynamic interaction, do not apply cefalexin simultaneously with pharmaceuticals acting bacteriostatically.

In order to ensure efficacy, the veterinary medicinal product should not be used in combination with bacteriostatic antibiotics.
Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.

3.9 Administration routes and dosage

Oral use
For urinary tract infections: 15 mg/kg body weight twice daily for 14 days.

For recurring severe dermatological infections: 25-30 mg/kg twice daily for at least three weeks. Treatment times of 4-6 weeks may be required for deep pyoderma. It is recommended to assess the benefit/risk and the duration of treatment after one month by the responsible veterinarian.
To ensure a correct dosage, body weight should be determined as accurately as possible. The tablets can be crushed or added to food, if necessary.

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

The acute symptom of cefalexin toxicity following an oral dose of 500 mg/kg has been shown to be vomiting. Salivating and individual emetic responses have been observed after oral doses of 200 and 400 mg/kg cefalexin over 365 days.

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

Not applicable.

3.12 Withdrawal period

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DB01

4.2 Pharmacodynamics

Cefalexin is a beta-lactam antibiotic in the first-generation cephalosporins. It inhibits bacterial cell membrane synthesis in a similar way to penicillin. Cephalosporins reduce the build-up of bacterial cell membranes, which leads to abnormal elongation of cells, formation of spheroplasts or osmotic lysis. In general, cephalosporins are bactericidal in effect. The bactericidal effect of cefalexin is mainly time dependent.

Antibacterial spectrum
Cefalexin is effective against Gram-positive cocci, including penicillinase-producing staphylococci, Gram-positive rods and Gram-negative bacteria, e.g. *E.coli.* Indole-positive *Proteus* species, excluding *P. Mirabilis*, are often resistant to cefalexin, as are certain *Enterobacteria* and *Bacteroides* species. Methicillin-resistant staphylococci are also generally resistant to cephalosporins, as are all enterococci and *Pseudomonas aeruginosa*.

Cephalosporins are however resistant in varying degrees to beta-lactamase produced by staphylococci and Gram-negative bacteria. Staphylococci sensitive to methicillin or oxacillin can be regarded as being sensitive to oral cephalosporins regardless of penicillinase production.

Development of resistance is mainly based on the formation of beta-lactamase, an enzyme that breaks open the beta-lactam ring, rendering the antibiotic ineffective. Cross resistance exists between antibiotics belonging to the beta-lactam group.

4.3 Pharmacokinetics

Peak plasma concentration (C_{max}) is between 19-32 microgram/ml, the time until C_{max} is achieved (T_{max}) is then 1-2 hours and the elimination half-life ($t_{1/2}$) is 1.7-2.8 hours when 25 mg cefalexin/kg body weight is administered orally to dogs.

The bioavailability of cefalexin is approx. 75% following oral administration.
A small proportion (18%) of cefalexin is bound to serum proteins in dogs.

Following a dose of 200 mg/kg, a low concentration of cefalexin activity was apparent in the brain, while no activity was apparent in the brain following a dose of 25 mg/kg. C_{max} in skin 2 hours after oral administration of 25 mg/kg cefalexin has been shown to be 7.3-10.8 microgram/g (20-40% of the plasma concentration). After 12 hours, the concentration had dropped to 1.4-1.7 microgram/g. The cefalexin concentration in kidneys is approximately quadruple the concentration in the blood.

Renal excretion is the main elimination path for cefalexin in dogs. Tubular secretion of cefalexin through the kidneys is dependent on the concentration of free cefalexin in the blood. Approximately 40% of an oral dose is excreted unaltered 24 hours after dose administration. Renal clearance of cefalexin is approximately 55-63 ml/min m^2 body surface.

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.

5.3. Special precautions for storage

Store below 25 °C in the original package in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

PVC/PVDC/Al blister.
250 mg: 14, 20, 28, 70 and 140 tablets
500 mg: 14, 28, 30, 70 and 140 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

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

2025-03-05

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).