PACKAGE LEAFLET

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. Composition

Each tablet contains:

Active substance:
Cefalexin monohydrate equivalent to 250 mg or 500 mg cefalexin.

Excipients:

Titanium dioxide (E171)	Kefavet vet 250 mg film-coated tablets: 0.550 mg Kefavet vet 500 mg film-coated tablets*:* 1.10 mg

Description of the tablet:
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. Target species

Dogs

4. Indications for use

For treatment of urinary tract infections and recurring severe dermatological infections in dogs.

5. Contraindications

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

6. Special Warnings

Special precautions for safe use in the target species:
In cases of known renal insufficiency, the dose must be reduced. Use of the product should be based on susceptibility testing and it should take into account official and local antimicrobial policies. Inappropriate use of the product may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness 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:
Cephalosporins and penicillins 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.

Pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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.

Major incompatibilities:

In the absence of incompatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, 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.

7. Adverse events

Dogs

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

*Most often mild.

In case of serious adverse effects in the stomach or intestines the treatment should be discontinued and a veterinary surgeon should be contacted.

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 {national system details}.

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

Oral use

The dosage is individually adjusted for the animal. Follow the veterinary surgeon´s instructions.
The tablets may be given directly into the mouth of the animal or crushed and added to food.

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of sight and reach of children.
Store below 25 °C in the original package in order to protect from light and moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the label 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

MA number

Package sizes:
250 mg: Blister with 14, 20, 28, 70 and 140 tablets
500 mg: Blister with 14, 28, 30, 70 and 140 tablets
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

2025-03-05

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:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:
Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Local representatives and contact details to report suspected adverse reactions: