PACKAGE LEAFLET FOR:

KEFAVET vet. 250 mg film-coated tablets
KEFAVET vet. 500 mg film-coated tablets

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

Marketing authorisation holder and manufacturer responsible for batch release:

Orion Corporation
P.O.Box 65
FI-02101 Espoo
Finland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

KEFAVET vet. 250 mg film-coated tablets
KEFAVET vet. 500 mg film-coated tablets
cefalexin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One tablet contains: Cefalexin monohydrate equivalent to 250 mg or 500 mg anhydrous cefalexin.
Other ingredients: Lactose monohydrate, saccharin sodium, titanium dioxide (E171)

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.

4. INDICATIONS

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. ADVERSE REACTIONS

Slight diarrhoea and vomiting has been observed, usually at the beginning of the treatment period. In case of serious adverse effects in the stomach or intestines the treatment should be discontinued and a veterinary surgeon should be contacted.

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

7. TARGET SPECIES

Dog

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

The dosage is individually adjusted for the animal. Follow the veterinary surgeon´s instructions.
Kefavet vet. 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 PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
Store below 25 °C in the original package. Protect from light and moisture.
Do not use after the expiry date stated on the package.

12. SPECIAL WARNINGS

Special precautions for use in animals:

In cases of known renal insufficiency, the dose must be reduced. The veterinary surgeon gives the new dosage.
Inappropriate use of the product may increase the prevalence of bacteria resistant to cefalaxin 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:

Cephalosporins and penicillins may cause hypersensivity reactions (allergy) following injection, inhalation, ingestion or skin contact. Hypersensivity to penicillins may lead to cross-reactions to cephalosporins 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.

Use during 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.

Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.

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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

18 July 2014

15. OTHER INFORMATION

Package sizes:
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.

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