1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine 75 mg Tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Cefalexin ……75 mg
(as Cefalexin Monohydrate)

Excipients:

Qualitative composition of excipients and other constituents
Crospovidone
Mannitol
Starch pregelantinised
Croscarmellose sodium
Collodial anhydrous silica
Collodial hydrated silica
Povidone K30
Microcrystalline cellulose type A
Poultry liver powder
Magnesium stearate
Microcrystalline cellulose type B

Creamy oblong tablets with small brown spots with a score-line.
The tablets can be divided into halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

For the treatment of bacterial skin infections in dogs (including deep and superficial pyodermas) caused by organisms susceptible to cefalexin.
For the treatment of cutaneous and subcutaneous infections (wounds and abscesses) in cats caused by organisms susceptible to cefalexin.
For the treatment of urinary-tract infections in cats and dogs (including nephritis and cystitis) caused by organisms susceptible to cefalexin.

3.3 Contraindications

Do not use in cases of hypersensitivity to penicillins and cephalosporins.
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:

As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In case of known renal insufficiency, the dose should be reduced and antimicrobials known to be nephrotoxic should not be administered concurrently.
This product should not be used to treat puppies of less than 1 kg of bodyweight or kittens under 9 weeks of age.

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 other cephalosporins and penicillins, due to the potential for cross-resistance.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

As the tablets are palatable to animals there is a danger of excessive ingestion. The tablets must therefore be stored out of the reach of animals.

Local treatment of cutaneous and subcutaneous infections in cats should be considered as a complement of the antibiotic treatment.

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 sensitivity to cephalosporin and *vice versa*. Allergic reactions to these substances may occasionally be serious.

1- Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Common (1 to 10 animals / 100 animals treated):	Vomiting[1,2,3] Diarrhoea[1,2,3]

Rare (1 to 10 animals / 10,000 animals treated):	Hypersalivation Increased drinking Hypersensitivity reaction[4] (e.g Allergic skin reaction, Hives, Allergic oedema, Abnormal breathing, Circulatory disorder)

[1] Mild and transient
[2] In most cases, these effects only lasted a day. They were reversible without administering symptomatic treatment and without interrupting treatment with the veterinary medicinal product.
[3] If vomiting and/or diarrhea occurs repeatedly, treatment should be discontinued and the advice of the treating veterinarian sought.
[4] In animals sensitive to penicillins/cephalosporins.

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Lethargy
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[1] (e.g Allergic skin reaction, Hives, Allergic oedema, Abnormal breathing, Circulatory disorder)
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Vomiting[2], Diarrhoea[2]

[1] In animals sensitive to penicillins/cephalosporins.
[2] If vomiting and/or diarrhea occurs repeatedly, treatment should be discontinued and the advice of the treating veterinarian 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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

The association of first-generation cephalosporins with aminoglycoside antibiotics and some diuretics such as furosemide can enhance nephrotoxicity risks.
The bactericidal activity of cephalosporins is reduced by concomitant administration of bacteriostatic acting compounds (tetracyclines, chloramphenicol, macrolides and rifampicin).

3.9 Administration routes and dosage

15 mg of cefalexin per kg of bodyweight twice daily (equivalent to 30 mg per kg of bodyweight per day) for a duration of:
- 5 days in case of cutaneous and subcutaneous infections (wounds and abscesses) in cats;
- 14 days in case of urinary-tract infection in cats and dogs;
- at least 15 days in case of superficial infectious dermatitis in dogs;
- at least 28 days in case of deep infectious dermatitis in dogs.

To achieve this dosage, administer:
in cats and dogs:

- one tablet per 5 kg of bodyweight or ½ tablet per 2.5 kg of bodyweight.

To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
Due to its palatable formulation, the product is well accepted by cats and dogs but may be crushed or added to food if necessary.
In severe or acute conditions, the dose may be safely doubled.

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

Trials performed on animals with up to 5 times the recommended dose of 15 mg/kg demonstrated that the product is well tolerated.

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 periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DB01.

4.2 Pharmacodynamics

The active ingredient of product is cefalexin monohydrate.

Cefalexin is a bactericidal antibiotic of the cephalosporin family which acts by inhibiting the nucleopeptide synthesis of the bacterial wall. It is obtained by hemi-synthesis from the 7-amino cephalosporanic nucleus. Cephalosporins interfere with transpepditation by acylating the enzyme making it unable to cross-link muramic acid-containing peptidoglycan strands. The inhibition of the biosynthesis of the material required to build the cell wall results in a defective cell wall which is consequently osmotically unstable. The combined action results in cell lysis and filament formation.
Cefalexin is active against a wide range of gram-positive and gram-negative aerobic bacteria: *Staphylococcus* spp. (including penicillin-resistant strains), *Streptococcus* spp., *Escherichia coli*, *Klebsiella* spp., *Salmonella* spp. and *Pasteurella multocida*. Cefalexin is not inactivated by β-lactamases produced by gram-positive bacteria and which usually affect penicillins.
Cefalexin had a time-dependent bactericidal activity on both tested bacteria species, *Staphylococcus felis* (gram-positive) and *Pasteurella multocida* (gram-negative).
In vitro activity of cefalexin towards European strains isolated in 2003-2006 in cats exhibiting cutaneous or subcutaneous infections showed that the MIC90 was 2 µg/ml for *Staphylococcus* spp. and *Pasteurella* spp. and 0.5 µg/ml for *Streptococcus* spp. These susceptible genera were also the bacteria the most-frequently isolated from wounds and abscesses in cats.

Resistance to cefalexin may be due to one of the following mechanisms of resistance. Firstly, the production of various beta-lactamases (cephalosporinase), that inactivate the antibiotic, is the most prevalent mechanism among gram-negative bacteria. Secondly, a decreased affinity of the PBPs (penicillin-binding proteins) for β-lactam drugs is frequently involved for β-lactam resistant gram-positive bacteria. Lastly, efflux pumps, extruding the antibiotic from the bacterial cell, and structural

changes in porins, reducing passive diffusion of the drug through the cell wall, may contribute to improve the resistant phenotype of a bacterium.
Well-known cross-resistance (involving the same resistance mechanism) exists between antibiotics belonging to the β-lactam group due to structural similarities. It occurs with β-lactamases enzymes, structural changes in porins or variations in efflux pumps. Co-resistance (different resistance mechanisms involved) has been described in *Escherichia.coli* due to a plasmid harbouring various resistance genes.

4.3 Pharmacokinetics

Dogs:
After single oral administration of the recommended dosage of 15 mg of cefalexin per kg of bodyweight to Beagle dogs, plasma concentrations were observed within 30 minutes. The plasma peak was observed at 1.3 hour with a plasma concentration of 18.2 µg/ml.
The bioavailability of the active was over 90 %. Cefalexin was detected until 24 hours after the administration. The first urine specimen was collected within 2 to 12 hours with peak concentrations of cefalexin measured at 430 to 2758 µg/ml within 12 hours.

After repeated oral administration of the same dosage, twice a day for 7 days, plasma peaks occurred 2 hours later with a concentration of 20 µg/ml. Over the treatment period, concentrations were maintained above 1 µg/ml. The mean elimination half-life is 2 hours. Skin levels were around 5.8 to 6.6 µg/g, 2 hours after treatment.

Cats:
A single oral administration of 15 mg of cefalexin per kg of bodyweight in cats led to a bioavailability of 56 %. The plasma peak was observed at 1.55 hour following administration with a plasma concentration above 15.1 µg/ml. The mean plasma half-life was about 1 to 2 hours. The first urine specimen was collected between 4 and 24 hours with the highest concentrations ranging between 63.7 and 393 µg/ml, occurring within 24 hours.

With the same dosage administered over 7 days, twice a day, the highest urine concentration of cefalexin reached between 518 and 1256 µg/ml.

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

Keep the blisters in the outer carton in order to protect from light.
Divided tablets should be stored in blister packs.

5.4 Nature and composition of immediate packaging

Blister packs consisting of blister aluminium – PVC/aluminium/OPA.
Aluminium foil lid coated with lacquer.

Cardboard box with 2 blisters of 7 tablets

Cardboard box with 20 blisters of 7 tablets
Cardboard box with 30 blisters of 7 tablets

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/018/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

27/07/2024

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).