

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with blisters of 7 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine 75 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Cefalexin75 mg
(as Cefalexin Monohydrate)

3. PACKAGE SIZE

Cardboard box of 30 blisters of 7 tablets

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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:

Twice daily, one tablet per 5 kg of bodyweight or ½ tablet per 2.5 kg of bodyweight.

To ensure correct dosage, bodyweight 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.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/4131

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

Blister 75 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

75 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rilexine 75 mg Tablet for dogs and cats

Rilexine 300 mg Tablet for dogs

Rilexine 600 mg Tablet for dogs

2. Composition

Each tablet contains:

Active substance;

Cefalexin (as Cefalexin Monohydrate):

Rilexine 75 mg Tablets for dogs and cats	75 mg
Rilexine 300 mg Tablets for dogs	300 mg
Rilexine 600 mg Tablets for dogs	600 mg

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

3. Target species

Dogs (75, 300 and 600 mg) and cats (75 mg).

4. Indications for use

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.

5. Contraindications

Do not use in animals which are known to be hypersensitive to penicillins and cephalosporins.

Do not use in rabbits, guinea pigs, hamsters and gerbils.

6. Special warnings

Special precautions for 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 paragraph : “ Dosage for each species, route and method of administration”, 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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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).

Overdose:

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

7. Adverse events

Rilexine 75 mg

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. Allergic cross-reactivity with other β -lactam may occur.

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. Allergic cross-reactivity with other β -lactam may occur.

² If vomiting and/or diarrhea occurs repeatedly, treatment should be discontinued and the advice of the treating veterinarian sought.

Rilexine 300 / 600 mg

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. Allergic cross-reactivity with other β -lactam may occur.

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 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

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:

Rilexine 75 mg Tablets for dogs and cats:

Twice daily, one tablet per 5 kg of bodyweight or ½ tablet per 2.5 kg of bodyweight.

Rilexine 300 mg Tablets for dogs:

Twice daily, one tablet per 20 kg of bodyweight or ½ tablet per 10 kg of bodyweight.

Rilexine 600 mg Tablets for dogs:

Twice daily, one tablet per 40 kg of bodyweight or ½ tablet per 20 kg of bodyweight.

To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the blisters in the outer carton in order to protect from light.

Divided tablets should be stored in blister packs.

Do not use this veterinary medicinal product after the expiry date which is stated on the 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.

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

Rilexine 75 mg Tablets for dogs and cats Vm 05653/4131

Rilexine 300 mg Tablets for dogs Vm 05653/4133

Rilexine 600 mg Tablets for dogs Vm 05653/4132

Cardboard Box with 30 blisters of 7 tablets.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1^{ère} avenue 2065m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:

Virbac Ltd
Suffolk, IP30 9UP – UK
Tel: +44 (0)-1359 243243

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

17. OTHER INFORMATION

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Gavin Hall
Approved: 25 July 2025