

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine TM 300 mg Tablets for dogs

STATEMENT OF ACTIVE SUBSTANCE

One tablet contains:

-Active substance

Cefalexin300 mg
(as Cefalexin Monohydrate)

PHARMACEUTICAL FORM

Tablets.

Creamy oblong tablets with small brown spots marked with a score-line.

The tablets can be divided into halves.

4. PACKAGE SIZE

Cardboard box of 30 blisters of 7 tablets

TARGET SPECIES

Dogs.

INDICATIONS

For the treatment of bacterial skin infections in dogs (including deep and superficial pyodermas) caused by organisms susceptible to Cefalexin.

For the treatment of urinary-tract infections in dogs (including nephritis and cystitis) caused by organisms susceptible to Cefalexin.

METHOD AND ROUTE 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:

- 14 days in case of urinary-tract infection in 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 dogs:

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

To ensure a 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 dogs but may be crushed or added to food if necessary.

In severe or acute conditions, the dose may be safely doubled.

WITHDRAWAL PERIOD

Not applicable.

SPECIAL WARNINGS

User warnings: Please read the package leaflet before use.

EXPIRY DATE

EXP {month/year}

SPECIAL STORAGE CONDITIONS

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

Divided tablets should be stored in blister packs.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF

For animal treatment only.

To be supplied only on veterinary prescription.

POM-V

THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue 2065 m – LID
06516 Carros
France

MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4133

MANUFACTURER'S BATCH NUMBER

Lot: {number}

Cardboard Box with 30 blisters of 7 tablets.

POM-V

 Distributeur : Virbac Ltd – Suffolk IP30 9 UP - UK

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister of 7 tablets

NAME OF THE VETERINARY MEDICINAL PRODUCT

RilexineTM 300 mg Tablets for dogs
(Cefalexin Monohydrate)

NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac

EXPIRY DATE

EXP {month/year}

BATCH NUMBER

Lot: {number}

THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

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 :

Virbac
1ère avenue 2065 m – LID
06516 Carros
France

NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine TM 75 mg Tablet for dogs and cats

Rilexine TM 300 mg Tablet for dogs

Rilexine TM 600 mg Tablet for dogs

STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One tablet contains Cefalexin (as Cefalexin Monohydrate):

Rilexine 75 mg Tablets for dogs and cats	75 mg
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Rilexine 300 mg Tablets for dogs	300 mg
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Rilexine 600 mg Tablets for dogs	600 mg
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Creamy oblong tablet with small brown spots marked with a score line.

The tablets can be divided into halves.

INDICATIONS

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.

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.

ADVERSE REACTIONS

Very rare cases of soft faeces and vomiting may be observed in animals during treatment.

Hypersensitivity to Cefalexin is rare, however, the product should not be administered to animals which are known to be hypersensitive to Cefalexin or penicillin. Allergic cross-reactivity with other β -lactams may occur.

TARGET SPECIES

Cats and dogs.

DOSAGE FOR EACH SPECIES, ROUTE 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.

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.

WITHDRAWAL PERIOD

Not applicable.

SPECIAL STORAGE PRECAUTIONS

Keep the blisters in the outer carton in order to protect from light.
Divided tablets should be stored in blister packs.
Keep out of the sight and reach of children

SPECIAL WARNINGS

Special precautions for use in animals:

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, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more-serious symptoms and require urgent medical attention.

Pregnancy, lactation or lay :

The product can be used in pregnant and lactating animals.

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 (symptoms, emergency procedures, antidotes):

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

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 products should be disposed of in accordance with local requirements.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2016

OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

Cardboard Box with 30 blisters of 7 tablets.

Rilexine 75 mg Tablets for dogs and cats UK : Vm05653/4131

Rilexine 300 mg Tablets for dogs Vm 05653/4133

Rilexine 600 mg Tablets for dogs Vm 05653/4132

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Distributeur : Virbac Ltd – Suffolk IP30 9 UP - UK

Approved: 17/08/2017

