TREATING DOGS WITH PYODERMA IS NO LONGER SUCH A BITTER HUMAN PILL TO SWALLOW.

Introducing RILEXINE® (cephalexin) Chewable Tablets for Dogs

The first veterinary approved cephalexin makes treating superficial bacterial pyoderma feel more like giving a treat.

Why hassle with capsules when RILEXINE® (cephalexin) Chewable Tablets give you so many options for precise dosing?

✔ Three sizes of tablets and scoring make it easier to prescribe the exact dose your canine patient needs.

✔ Scored tablets are ideal for BID dosing and can help minimize the daily cost of therapy.

✔ FDA-approved mg/kg dosage strengths for your canine patients can help prevent the side effects associated with inaccurate dosing.

By combining palatability with canine-friendly dosing, RILEXINE Chewable Tablets are your best value.

RILEXINE Chewable Tablets are not for use in dogs with a history of allergic reactions to penicillins or cephalosporins. Sensitized individuals should avoid contact of the product with the skin and mucous membranes. The safety of RILEXINE Chewable Tablets in breeding, pregnant, or lactating bitches has not been evaluated.

Contact your Midwest Veterinary Supply Representative for more information!
To place your order: 1-800-643-9378 | www.midwestvet.net
**RILEXINE®** (Cephalexin) Chewable Tablets for Dogs

**INDICATION:** For the treatment of secondary superficial bacterial pododermatitis in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*.

**DOSAGE AND ADMINISTRATION:** The recommended dose is 22 mg/kg (10 mg/lb) of body weight twice daily for 28 days. Appropriate culture and susceptibility tests should be performed before treatment to determine the causative organism(s) and susceptibility to cephalexin. Therapy with RILEXINE Chewable Tablets may be initiated before results of these tests are known; if the organism identified is susceptible to cephalexin, treatment should be continued. If an organism is not identified, then the diagnosis should be re-evaluated and appropriate alternative therapy considered.

**CONTRAINDICATIONS:** RILEXINE Chewable Tablets are contraindicated in dogs with a known allergy to cephalexin or to the β-lactam family of antibiotics.

**WARNINGS:** For use in dogs only. Not for use in humans. Keep this drug out of the reach of children. Antimicrobials, including cephalexin and cephalexin, can cause allergic reactions in sensitized individuals. Sensitized individuals handling such antimicrobials, including cephalexin, should avoid contact of the product with the skin and mucous membranes in order to minimize the risk of allergic reactions.

In case of ingestion by humans contact a physician immediately. Physicians may contact a Poison Center for advice concerning cases of ingestion by humans.

To obtain a copy of the Material Safety Data Sheet (MSDS), or to report adverse reactions, call Virbac at 1-800-338-3659.

**PRECAUTIONS:** Prescribing antibiotic drugs in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant animal pathogens.

The safety and efficacy of RILEXINE Chewable Tablets in dogs intended for breeding and in pregnant or lactating bitches has not been evaluated.

Positive direct Coombs’ test results and false positive Coombs’ tests in dogs have been reported during treatment with some cephalosporin antimicrobials. Cephalosporin antimicrobials may also cause falsely elevated urine protein determinations. Some antimicrobials, including cephalexin, can cause lowered serum albumin values due to interference with certain testing methods. Occasionally, cephalosporins have been associated with myelotoxicity, thereby creating a toxic neutropenic reaction. Hemolytic anemia, which has been noted with all β-lactams, is the reaction observed with cephalosporin therapy including neutropenia, anemia, hyperprothrombocytopenia, thrombocytopenia, 4.8 hrs for a BID dosing regimen, and for streptococcal infections, the target for time above MIC is 90% of the dosing interval (36 hrs).

**ADVERSE REACTIONS:** The most common adverse reactions in dogs include: diarhoea, gastrointestinal disease, anorexia, and lethargy. To report suspected adverse reactions call Virbac at 1-800-338-3659.

A total of 78 dogs were included in the field study safety analysis. Adverse reactions reported in dogs treated with RILEXINE Chewable Tablets and placebo are summarized in Table 1. Table 1: Number of Adverse Reactions Reported During the Field Study with RILEXINE Chewable Tablets

**PHARMACOKINETICS:** Cephalexin is a cephalosporin antibiotic. Like other β-lactam antimicrobials, cephalexin exerts its inhibitory effect by interfering with bacterial cell wall synthesis. This interference is primarily due to its covalent binding to the penicillin-binding proteins (PBP) (i.e., enzymes necessary for peptidoglycan synthesis which are essential for synthesis of the bacterial wall). Minimum Inhibitory Concentrations (MICs) for cephalexin against lactic acid bacteria isolated from canine pododermatitis in a 2008-2009 U.S. field trial are presented in Table 1. All MICs were determined in accordance with the Clinical Laboratory Standards Institute (CLSI) standards.

**MICROBIOLOGY:** Cephalexin is a cephalosporin antibiotic. Like other β-lactam antimicrobials, cephalexin exerts its inhibitory effect by interfering with bacterial cell wall synthesis. This interference is primarily due to its covalent binding to the penicillin-binding proteins (PBP) (i.e., enzymes necessary for peptidoglycan synthesis which are essential for synthesis of the bacterial wall). Minimum Inhibitory Concentrations (MICs) for cephalexin against lactic acid bacteria isolated from canine pododermatitis in a 2008-2009 U.S. field trial are presented in Table 1. All MICs were determined in accordance with the Clinical Laboratory Standards Institute (CLSI) standards.

**PK-PD targets.** The clinical effectiveness of RILEXINE Chewable Tablets was established in a randomized, multi-location, placebo-controlled (n = 12) study. In this study, 113 dogs with secondary superficial bacterial pododermatitis treated with either RILEXINE Chewable Tablets (n = 91) at 22 mg/kg (10 mg/lb) body weight or with a negative control (n = 42), twice daily for 28 days, were analyzed. RILEXINE Chewable Tablets were considered superior to the placebo (70% success rate vs. 33% respectively in the treatment of primary bacterial superficial bacterial pododermatitis caused by susceptible strains of *Staphylococcus pseudintermedius*).

Table 4: Primary endpoint: Percentage of Cure* (Effectiveness population)

**ED TESTS:** Cephalosporins are associated with time-dependent killing effects. Accordingly, the pharmacodynamic (PD) target for time above MIC (T >MIC). For staphylococcal infections, the goal for time above MIC is 90% of the dosing interval (36 hrs).

**SAFETY:** RILEXINE Chewable Tablets were administered orally three times a day to 12-week-old healthy Beagles at 0 mg/kg (placebo), 22 mg/kg (1X), 66 mg/kg (3X), and 110 mg/kg (5X) for 12 weeks, and at 22 mg/kg twice a day for 12 weeks. The most common clinical findings included epistaxis, salivation, vomiting and diarrhea among all the dose groups. Three dogs had decreased activity (1 each from the 22 mg/kg twice a day, 22 mg/kg three times a day, and the 66 mg/kg three times a day groups). These observations were mild and sporadic.

There were increases in alanine aminotransferase (ALT) in the 110 mg/kg three times a day group and in the 22 mg/kg twice a day group that increased in a dose-dependent manner. There was an increase in sorbitol dehydrogenase (SDH) in the 110 mg/kg three times a day group compared to the controls. These changes were minimal and the values remained within expected historical control ranges. There were increases in total protein in the 110 mg/kg three times a day group and/or globulin in the 22, 66, and 110 mg/kg three times a day groups compared to the controls. These changes were minimal and resulted in occasional increases in albumin/ globulin ratios. Although a drug effect cannot be ruled-out, these changes were not clinically relevant.

A mild prolongation in prothrombin time (PT) was observed in the 22 mg/kg three times a day group. This was not considered clinically relevant due to the small change that remained within the reference range.

One dog in the 110 mg/kg three times a day group had moderate amounts of bilirubinuria at the Week 8 and 12 samplings. No clinical significance was noted.

Cephalexin was not present in any Day 1 samples prior to dosing or in any control animals. After dosing, cephalexin was well absorbed into systemic circulation of the treated dogs. Within gender and dosage level, Week 8 mean trough concentrations were generally higher than the Week 4 and 12 mean trough concentrations (between a 1.3 to 1.9 fold decrease in mean trough concentrations between the same gender, same dose groups). There was a geometric mean plasma cephalaxin trough concentration following three times daily administration of the 110 mg/kg dose that decreased by 2.6 µg/mL and 8.7 µg/mL following 22 mg/kg and 66 mg/kg, respectively at Week 12. Geometric mean plasma cephalaxin trough concentration following administration of 22 mg/kg twice daily were 0.7 µg/mL and 1.0 µg/mL at Weeks 4, 8, and 12, respectively.

**STORAGE INFORMATION:** Store at 20°C-25°C (68°F-77°F), with excursions permitted between 15°C-30°C (59°F-86°F).

**HOW SUPPLIED:** RILEXINE (cephalexin) Chewable Tablets are supplied in 75 mg, 150 mg, 300 mg, and 600 mg tablets packaged in bottles of 100 and 200 tablets, in boxes of 28 blister packs of 7 tablets per blister pack.

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