CLAVAMOX® CHEWABLE

(penicillin and clavulanic acid combination tablet)

**Chewable Tablets**

Antibacterial For Oral Use In Dogs And Cats

**CAUTION:** (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION:** CLAVAMOX CHEWABLE Tablet (amoxicillin and clavulanate potassium tablets) is an orally administered formulation comprised of the broad-spectrum antibiotic Amoxi® (amoxicillin trihydrate) and the β-lactamase inhibitor clavulanate potassium (the potassium salt of clavulanic acid).

Amoxicillin trihydrate is a penicillin derivative with a broad spectrum of bactericidal activity against many gram-positive and gram-negative aerobic and anaerobic microorganisms. It does not resist destruction by β-lactamase; therefore, it is not effective against β-lactamase-producing bacteria. Chemically, it is (S)-2-amino-6-hydroxy-7-[[(2R,5R)-2,5-dimethyl-3-thiazolidinyl]amino]-3-cephem-4-carboxylic acid.

Clavulanic acid, an inhibitor of β-lactamases, is produced by the fermentation of Streptomyces clavuligerus. Clavulanic acid itself has only weak antibacterial activity. Chemically, clavulanic potassium is potassium (the potassium salt of clavulanic acid).

**INDICATIONS:** CLAVAMOX CHEWABLE Tablets are indicated in the treatment of:

**Dogs:** Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/aureus and deep pyodermas due to susceptible strains of the following organisms: *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*. Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria. CLAVAMOX CHEWABLE Tablets has been shown to be clinically effective for treating cases of canine periodontal disease.

**Cats:** Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: *β-lactamase-producing* *Staphylococcus* spp., *Streptococcus* spp., *Streptococcus* spp., and *E. coli*. Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria. CLAVAMOX CHEWABLE Tablets has been shown to be clinically effective for treating cases of feline periodontal disease.

**CAUTION:** Therapy may be initiated with CLAVAMOX CHEWABLE prior to obtaining results from bacteriological and susceptibility studies. A culture should be obtained prior to therapy to determine susceptibility of the organism to CLAVAMOX CHEWABLE. Following determination of susceptibility results, therapy should be discontinued if the organism is not susceptible to CLAVAMOX CHEWABLE.

**DOSAGE AND ADMINISTRATION:**

The dose should be prescribed using a combination of whole tablet strengths (62.5, 125, 250, or 375 mg) and the tablet should be broken up for oral administration if necessary. Each tablet contains 62.5 mg of amoxicillin trihydrate and 12.5 mg of clavulanic potassium (the potassium salt of clavulanic acid).

**Dogs:**

The recommended dosage of CLAVAMOX CHEWABLE Tablet is 25 mg/kg twice a day.

Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/aureus and deep pyodermas should be treated for 5-7 days or for 48 hours after symptoms have subsided. If no response is seen in 48 hours, the case should be discontinued and the case reevaluated. Unilateral pyodermic may require treatment for 27 days; the maximum duration of treatment should not exceed 30 days.

**Cats:**

The recommended dosage of CLAVAMOX CHEWABLE Tablet is 3.8 mg/kg twice a day.

Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis should be treated for 5-7 days or for 48 hours after symptoms have subsided; not to exceed 30 days. If no response is seen in 48 hours, the case should be discontinued and the case reevaluated. Unilateral pyodermic may require treatment for 10-14 days or longer. The maximum duration of treatment should not exceed 30 days.

**CONTRAINDICATIONS:**

The use of this drug is contraindicated in animals with a history of allergic reaction to any of the penicillins or cephalosporins, can cause allergic reactions in sensitized individuals. To minimize the possibility of allergic reactions, those handling such products should avoid direct contact of the product with the skin and mucous membranes.

**PRECAUTIONS:** Prescribing antibacterial drugs is 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. Safety of use in pregnant or breeding animals has not been determined.

**WARNING:** Store CLAVAMOX CHEWABLE out of reach of dogs, cats, and other pets in a secured location in order to prevent accidental ingestion or overdose. HUMAN WARNINGS:

Not for human use. Keep this and all drugs out of reach of children. Antimicrobial drugs, including penicillins and cephalosporins, can cause allergic reactions in sensitized individuals. To minimize the possibility of allergic reactions, those handling such products should avoid direct contact of the product with the skin and mucous membranes.

**ADVERSE REACTIONS:** CLAVAMOX CHEWABLE contains a tetracycline penicillin (amoxicillin) and this has the potential for producing allergic reactions. In an allergic reaction- victims, avoid amoxicillin and/or penicillins.

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**CLAVAMOX CHEWABLE TABS ROLL USA FI**

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CLAVAMOX CHEWABLE combines the distinctive properties of a broad-spectrum antibiotic and a β-lactamase inhibitor to effectively extend the antimicrobial spectrum of amoxicillin to include β-lactamase-producing aerobic and anaerobic organisms. The action of clavulanic acid extends the antimicrobial spectrum of amoxicillin to include organisms resistant to amoxicillin and other β-lactam antibiotics. Amoxicillin/clavulanate has been shown to have a wide range of activity, which includes β-lactamase-producing strains of both gram-positive and gram-negative organisms, facultative anaerobes, and obligate anaerobes. Many strains of the following organisms, including β-lactamase-producing, isolated from veterinary sources, were found to be susceptible to amoxicillin-clavulanate in vitro. The clinical significance of this activity has not been demonstrated for some of these organisms in animals.

Aerobic bacteria, including:

- β-lactamase-producing
- Staphylococcus species*.
- Staphylococcus epidermidis, Staphylococcus species*.
- Pasteurella multocida.
- Pasteurella hemolytica, Pasteurella species*.

The susceptibility of these organisms has also been demonstrated in in vitro and in vivo studies. Studies have demonstrated that both amoxicillin and clavulanate are isolated from gingival cultures of dogs with clinical evidence of periodontal disease. Both are isolated from gram-positive and gram-negative aerobic and anaerobic subgingival isolates indicating sensitivity to amoxicillin/clavulanate.

SUSCEPTIBILITY TEST:
The recommended quantitative disc susceptibility method (KOBACH, REGIER 13:2827-2832, 1990; Kirby, B. A. M., Sherris J. C., 1966) utilized the standardized single disc method. Amoxicillin-clavulanate (6.25 mg; 12.5 mg) is applied to a previously gassed plate and pre-cultured aerobic and anaerobic subgingival isolates indicate sensitivity to amoxicillin/clavulanate CHEWABLE Tablets.

PHARMA CODE:
The following adverse events are based on post-approval adverse drug reaction reports, and for dogs and cats are listed in decreasing order of reporting frequency for CLAVAMOX. Anemia, vomiting, lethargy, inappetence and diarrhea.

For dogs, the following adverse events reported for dogs and cats are listed in decreasing order of reporting frequency for CLAVAMOX: Anemia, vomiting, lethargy, inappetence and diarrhea. For cats, the following adverse events reported for dogs and cats are listed in decreasing order of reporting frequency for CLAVAMOX: Anemia, vomiting, lethargy, inappetence and diarrhea.

In addition to adverse drug reaction reports, other information is available. For additional information about adverse drug experience reporting for animals, contact FDA at 1-888-RX-VETS or at www.fda.gov/reportanimaladverse.