**CLAVAMOX CHEWABLE**

**(amoxicillin and clavulanate potassium tablets)**

**Chewable Tablets**

**Antimicrobial For Oral Use In Dogs And Cats**

**CAUTION:** Federal (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<sup>®</sup> (amoxicillin trihydrate) and the β-lactamase inhibitor, clavulinate potassium (the potassium salt of clavulanic acid).

Amoxicillin trihydrate is a semisynthetic antibiotic 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-lactamases; therefore, it is not effective against β-lactamase-producing bacteria. Chemically, it is (D-)(+)-α-amino-p-hydroxybenzyl penicillin trihydrate.

Clavulanic acid, an inhibitor of β-lactamase enzymes, is produced by the fermentation of *Streptomyces clavuligerus*. Clavulanic acid by itself has only weak antibacterial activity. Chemically, clavulinate potassium is potassium z-(3R,5R)-2-β-hydroxyethylidene clavam-3-carboxylate.

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

**Dogs:** Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: β-lactamase-producing *Staphylococcus aureus*, non-β-lactamase-producing *Staphylococcus aureus*, *Staphylococcus aureus*, *Staphylococcus intermedius*, *Streptococcus faecalis*, *Streptococcus faecium*, *S. pyogenes*, *Corynebacterium pyogenes*, *Corynebacterium species*, *Erysipelothrix rhusiopathiae*, *Bordetella bronchiseptica*, *Escherichia coli*, *Proteus mirabilis*, *Proteus species*, *Enterobacter species*, *Klebsiella pneumoniae*, *Salmonella dublin*, *Salmonella typhimurium*, *Pasteurella multocida*, *Pasteurella hemolytica*, *Pasteurella species*.

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


**PALATABILITY:** The palatability of CLAVAMOX CHEWABLE Tablets was evaluated in a multi-location field trial. One hundred twelve (112) client-owned dogs were dosed with CLAVAMOX CHEWABLE Tablets at 6.25 mg/lb (12.5 mg/kg) twice daily for 7 days and evaluated for palatability of the product. Dogs freely consumed 83% of their doses within 5 minutes of offering from an empty bowl or owner’s hand. Of the 17% of doses unconsumed after 5 minutes, 16% were administered with a treat/food or forced intake and 1% of doses were refused. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

**ACTIONS:** The 2 components are rapidly absorbed resulting in amoxicillin and clavulanic acid concentrations in serum, urine, and tissues similar to those produced when each is administered alone.

Amoxicillin and clavulanic acid diffuse readily into most body tissues and fluids with the exception of brain and spinal fluid, which amoxicillin penetrates adequately when meninges are inflamed. Most of the amoxicillin is excreted unchanged in the urine. Clavulanic acid’s penetration into spinal fluid is unknown at this time. Approximately 15% of the administered dose of clavulanic acid is excreted in the urine within the first 6 hours.

CLAVAMOX CHEWABLE combines the distinctive properties of a broad-spectrum antibiotic and a β-lactamase inhibitor to effectively extend the antibacterial spectrum of amoxicillin to include β-lactamase-producing as well as non-β-lactamase-producing aerobic and anaerobic organisms.

**MICROBIOLOGY:** Amoxicillin is bactericidal in action and acts through the inhibition of biosynthesis of cell wall mucopeptide of susceptible organisms. The action of clavulanic acid extends the antimicrobial spectrum of amoxicillin to include organisms resistant to amoxicillin and other β-lactam antibiotics. Amoxicillin/clavulane has been shown to have a wide range of activity which includes β-lactamase-producing strains of both gram-positive and gram-negative aerobes, facultative anaerobes, and obligate anaerobes. Many strains of the following organisms, including β-lactamase-producing strains, isolated from veterinary sources, were found to be susceptible to amoxicillin/clavulane in vitro but the clinical significance of this activity has not been demonstrated for some of these organisms in animals.

Aerobic bacteria, including *Staphylococcus aureus*, β-lactamase-producing *Staphylococcus aureus* (penicillin resistant), *Staphylococcus species*, *Staphylococcus epidermidis*, *Staphylococcus hominis*, *Streptococcus faecalis*, *Streptococcus faecium*, *Corynebacterium pyogenes*, *Corynebacterium species*, *Erysipelothrix rhusiopathiae*, *Bordetella bronchiseptica*, *Escherichia coli*, *Proteus mirabilis*, *Proteus species*, *Enterobacter species*, *Klebsiella pneumoniae*, *Salmonella dublin*, *Salmonella typhimurium*, *Pasteurella multocida*, *Pasteurella hemolytica*, *Pasteurella species*.

**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 antimicrobials, including amoxicillin and clavulanate potassium, are advised to avoid direct contact of the product with the skin and mucous membranes.

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

**ADVERSE REACTIONS:** CLAVAMOX CHEWABLE contains a semisynthetic penicillin (amoxicillin) and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids.

To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Zoetis Inc. at 1-888-963-8471 or www.zoetis.com.