

Clavamox Veterinary Tablets 250 mg

ACTIVE INGREDIENTS:

Each 250 mg tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin activity and 50 mg of clavulanic acid as the potassium salt.

PRODUCT DESCRIPTION:

Clavamox 250 mg tablets: White, film-coated, round and biconvex tablet debossed with "BMP/206".

PHARMACODYNAMICS: 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/clavulanate 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/clavulanate 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 intermedius*, *Streptococcus faecalis*, *Streptococcus* species*, *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 haemolytica*, *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.

PHARMACOKINETICS: Clavamox is stable in the presence of gastric acid and is not significantly influenced by gastric or intestinal contents. 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 combines the distinctive properties of a broad-spectrum antibiotic and β -lactamase inhibitors to effectively extend the antibacterial spectrum of amoxicillin to include β -lactamase-producing as well as non- β -lactamase-producing aerobic and anaerobic organisms.

INDICATIONS: Clavamox 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* spp., *Streptococcus* spp., and *E. coli*.

Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria. Clavamox has been shown to be clinically effective for treating cases of canine periodontal disease.

DOSAGE AND ADMINISTRATION: By oral.

Dogs: The recommended dosage is 6.25 mg/lb of body weight twice a day. Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyoderma, and periodontal infections should be treated for 5–7 days or for 48 hours after all symptoms have subsided. If no response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated. Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

CONTRAINDICATIONS: The use of this drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins or cephalosporins.

WARNING AND PRECAUTIONS: Do not remove from foil strip until ready to use.

INTERACTIONS WITH OTHER MEDICAMENTS: Before giving Clavamox, tell your veterinarian if your pet is being given another antibiotic.

PREGNANCY AND LACTATION: Safety of use in pregnant or breeding animals has not been determined.

ADVERSE EFFECTS: Clavamox contains a semisynthetic penicillin (amoxicillin) and has the potential for producing allergic reactions. If an allergic reactions occurs, administer epinephrine and/or steroids.

OVERDOSE AND TREATMENT: Stop medication and to seek for veterinarian advice if there is sign of over dosage.

STORAGE CONDITIONS: Store at temperature below 25°C.

DOSAGE FORM AND PACKAGING: Clavamox Tablets are supplied in strip packs. Each carton holds 15 strips with 14 tablets per strip (210 tablets per carton).

Manufactured by:

Aurobindo Pharma Limited
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Quthbullapur Mandal, R.R.

Product Registration Holder:

zoetis

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