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

DESCRIPTION: Clavamox (amoxicillin and clavulanate potassium tablets) is an orally administrated formulation comprised of the broad-spectrum antibiotic, Amoxicillin (amoxicillin trihydrate) and the β-lactamase inhibitor, clavulanate potassium (the potassium salt of clavulamic acid).

Amoxicillin trihydrate is a semi-synthetic 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-lactamase, therefore, it is not effective against β-lactamase-producing bacteria. Chemically, it is (D)-α-amino-p-hydroxybenzylamido 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, clavulanate potassium is potassium-2-(D)-β-lactam-3-carboxylate.

ACTIONS: Clavulanic acid 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 clavulanate acid concentrations in serum, urine, and tissues similar to those produced when each is administered alone.

Amoxicillin and clavulanate acid diffuse readily into most body tissues and fluids with the exception of bone and spinal fluid, which amoxicillin penetrates adequately when meningitis is inflamed.

Most of the amoxicillin is excreted unchanged in the urine. Clavulanate acid penetration into spinal fluid is unknown at this time. Approximately 15% of the administered dose of clavulanate acid is excreted in the urine within the first 8 hours.

Clavamox 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 peptidoglycans 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; 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*, Streptococcus pyogenes, Streptococcus faecalis, Streptococcus species*, Corynebacterium species, Corynebacterium pseudotuberculosis, Escherichia coli*, Proteus mirabilis, Proteus species, Enterobacter species, Klebsiella pneumoniae, Enterococcus faecalis, Proteus species, Pseudomonas aeruginosa, 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 anaerobic and anaerobic subgingival isolates include a variety of amoxicillin/ clavulanate sensitive and resistant strains. The drug is most active against aerobic aerobic and act against a variety of anaerobic organisms.

INDICATIONS: Clavamox Tablets are indicated in the treatment of:

Dogs: Skin and soft tissue infections such as abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: β-lactamase-producing *Staphylococcus aureus*, *Streptococcus spp.*, *Pasteurella spp.*, *E. coli*, and *Escherichia 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 cutaneous periodontal disease.

Cats: Skin and soft tissue infections such as abscesses, cellulitis, and cellulitis/pyodermata due to susceptible strains of the following organisms: β-lactamase-producing *Staphylococcus aureus*, non-β-lactamase-producing *Staphylococcus aureus*, *Streptococcus spp.*, *Escherichia coli*, and *Pasteurella spp.*. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

Therapy may be initiated with Clavamox prior to obtaining results from bacteriological and susceptibility studies. A culture should be obtained prior to treatment to determine susceptibility of the organisms to Clavamox. Following determination of susceptibility results and clinical response to medication, therapy may be reevaluated.

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

WARNings: Safety of use in pregnant or breeding animals has not been determined. Store in a dry, cool place at temperatures not above 20°C (70°F).

Do not remove from foil strip until ready to use.

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

Post-Approval Experience (July, 2017): For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

DOSAGE AND ADMINISTRATION: Dogs: The recommended dosage is 25 mg/kg 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.

Cats: The recommended dosage is 62.5 mg/kg twice a day.

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

HOW SUPPLIED: Clavamox Tablets in the following strengths are supplied in strip packs. Each carton holds 15 tablets per carton.

- Each 62.5-mg tablet contains amoxicillin trihydrate equivalent to 50 mg of amoxicillin activity and 25 mg of clavulanic acid as the potassium salt. For use in dogs and cats.
- Each 125-mg tablet contains amoxicillin trihydrate equivalent to 100 mg of amoxicillin activity and 25 mg of clavulanic acid as the potassium salt. For use in dogs only.
- Each 250-mg tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin activity and 75 mg of clavulanic acid as the potassium salt. For use in dogs only.
- Each 625-mg tablet contains amoxicillin trihydrate equivalent to 250 mg of amoxicillin activity and 125 mg of clavulanic acid as the potassium salt. For use in dogs only.

Dispense according to recommendations outlined in Dosage and Administration section.

NADA #55-099, Approved by FDA.

Distributed by: Zoetis Inc.

Kalamazoo, MI 49007

Revised: September 2017
MADE IN INDIA

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zoetis GLOBAL EXTERNAL SUPPLY

Date: 11 Sep 2017

Time: 11 : 59

Proof Nº 02

Description
LEAFLET CLAVAMOX TABLETS USA

Artwork Code
P1515962

Component
Leaflet

Supplier
Aurobindo

Pharma Code
15962

Market
USA

SKU N
319475

Drawn by
N/A

Perigord Nº
200004050

Colours
black

Tel: +353 (01) 440 3222

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TEXT SIZE

on this A/W is at: 6.75 pt

Dimensions
2 3/4” x 10 5/8”

Drawing Number
N/A

SKU Nº
N/A