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

DESCRIPTION: Clavamox® (amoxicillin and clavulanic potassium tablets), USP, is an orally administered combination comprised of the broad-spectrum antibiotic, amoxicillin (benzyl penicillin trihydrate) and β-lactamase inhibitor, clavulanic potassium (the potassium salt of clavulanic acid).

Amoxicillin trihydrate is a semisynthetic antibiotic with a broad spectrum of bacterial 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-β-hydroxyvaleric acid or clavulanate 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-[[(2R,5R)-2-hydroxybenzylidene clavam-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 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 meningitis are infected. Most of the amoxicillin is recovered unchanged in the urine. Clavulanic acid penetrates into spinal fluid in amounts at this time. Approximately 15% of the administered dose of clavulanic acid is excreted in the urine within the first 8 hours.

Clavulanate potassium penetrates into most body tissues adequately when meninges are inflamed. Amoxicillin and clavulanic acid diffuse readily into most body tissues with the exception of brain and spinal fluid, which amoxicillin penetrates adequately when meningitis are infected. Most of the amoxicillin is recovered unchanged in the urine. Clavulanic acid penetrates into spinal fluid in amounts at this time. Approximately 15% of the administered dose of clavulanic acid is excreted in the urine within the first 8 hours.

Microbiology: Amoxicillin is bactericidal in action and acts through the inhibition of biosynthesis of cell wall susceptible to organism.

The action of clavulanic acid extends the antimicrobial spectrum of amoxicillin to include organisms resistant to amoxicillin and other β-lactam antibiotics. Amoxicillin/ clavulanic acid 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/ clavulanic acid in vitro. The clinical significance of this activity has not been demonstrated for some of these organisms in animals.

Gram-negative bacteria, including Staphylococcus aureus*, β-lactamase-producing (Staphylococcus aureus* penicillin resistant), Staphylococcus epidermidis, Staphylococcus intermedius, Streptococcus faecalis, Streptococcus species*, Corynebacterium species, Erysipelothrix rhusiopathiae, Bordetella bronchiseptica, Escherichia coli*, Proteus mirabilis, Proteus species, Enterobacter species, Klebsiella pneumoniae, Salmonella species, Salmonella typhimurium, Proteus mirabilis, Proteus vulgaris, Proteus species*.

* The susceptibility of these organisms has also been demonstrated in vivo studies. Studies have demonstrated that both aerobic and anaerobic aerobic and anaerobic subgroups indicate susceptibility.
The following adverse events are listed in decreasing order of reporting frequency for CLAVAMOX. Anorexia, lethargy, vomiting and diarrhea.

To report suspected adverse reactions, to obtain a Safety Data Sheet, or for technical assistance, call 1-888-963-8471.

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.

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.

Combination of amoxicillin with clavulanic acid is resistant to degradation by β-lactamase. Clavamox has been shown to be clinically effective for treating cases of canine periodontal disease.

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.

The following adverse events reported for dogs and cats are listed in decreasing order of reporting frequency for CLAVAMOX. Anorexia, lethargy, vomiting and diarrhea.

To report suspected adverse reactions, to obtain a Safety Data Sheet, or for technical assistance, call 1-888-963-8471.

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.

DOSEAGE AND ADMINISTRATION:

Dogs: The recommended dosage is 25 mg of body weight twice a day.

Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyodermas, 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 re-evaluated.

Deep pyodermas may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

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

Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyodermas, 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 re-evaluated. Deep pyodermas may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

SUPPLIED: Clavamox Tablets in the following strengths are supplied in strip packs. Each carton holds 15 strips with 14 tablets per strip (210 tablets per carton):

- Each 125 mg tablet contains amoxicillin trihydrate equivalent to 100 mg of amoxicillin activity and 12.5 mg of clavulanic acid as the potassium salt. For use in dogs and cats.
- Each 250 mg tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin activity and 25 mg of clavulanic acid as the potassium salt. For use in dogs only.
- Each 375 mg tablet contains amoxicillin trihydrate equivalent to 300 mg of amoxicillin activity and 37.5 mg of clavulanic acid as the potassium salt. For use in dogs only.
- Each 500 mg tablet contains amoxicillin trihydrate equivalent to 400 mg of amoxicillin activity and 50 mg of clavulanic acid as the potassium salt. For use in dogs only.
- Each 625 mg tablet contains amoxicillin trihydrate equivalent to 500 mg of amoxicillin activity and 62.5 mg of clavulanic acid as the potassium salt. For use in dogs only.
- Each 1250 mg tablet contains amoxicillin trihydrate equivalent to 1000 mg of amoxicillin activity and 125 mg of clavulanic acid as the potassium salt. For use in dogs only.

The recommended dosage is 6.25 mg/lb of body weight twice a day.

Do not remove from foil strip until ready to use.

Profile
LEAFLET CLAVAMOX TABLETS USA_APL
CR Number
371319
SKU N°
N/A
Drawing Number
N/A
Dimensions
2 3/4" x 10 5/8"
Flat
N/A
2 3/4" x 10 5/8"

text size
6.75 pt

zoeis
Distributed by: Zoetis Inc.
Kalamazoo, MI 49007

Revised: February 2019
P1518421

zoetis
GLOBAL EXTERNAL SUPPLY
Date: 12 Feb 2019
Time: 14 : 44

Description
Artwork Code
Supplier
Market
Peri Gong Nº
Colours

LEAFLET CLAVAMOX TABLETS USA_APL
P1518421
Aurobindo India
USA
371319
Black

Component
Pharma Code
GTIN

Leeflet
18421
N/A
200006882

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E-mail: Perigord34@dsi.com

approved by FDA under NADA # 055-099

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