Clavacillin™

(amoxicillin trihydrate/clavulanate potassium) Veterinary Tablets

DOGS: Indicated in the treatment of periodontal and skin and soft tissue infections such as wounds, abscesses, cellulitis, and superficial/juvenile and deep pyoderma due to susceptible strains of bacteria.

CATS: Indicated in the treatment of urinary tract infections (cystitis) and skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of bacteria.

Expected to have the same safety and efficacy as the pioneer drug since it is therapeutically equivalent.

Available in 62.5 mg, 125 mg, 250 mg, and 375 mg tablets supplied in foil strip packs. Each carton holds 15 foil strip packs with 14 tablets per strip (210 tablets per carton).

Dechra
Veterinary Products

To order, please contact your Dechra or distributor representative or call (866) 683-0660.
For more information, please visit www.dechra-us.com

As with all drugs, side effects may occur. Clavacilllin Veterinary Tablets contain a semisynthetic penicillin (amoxicillin) and have the potential for producing allergic reactions. This product should not be used in animals with a history of an allergic reaction to any of the penicillins or cephalosporins. If an allergic reaction occurs, administer epinephrine and/or steroids. Refer to the prescribing information for complete details or visit www.dechra-us.com.

24-hour Veterinary Technical Support available (866) 933-2472.
Nonurgent Technical Support available via email support@dechra.com.

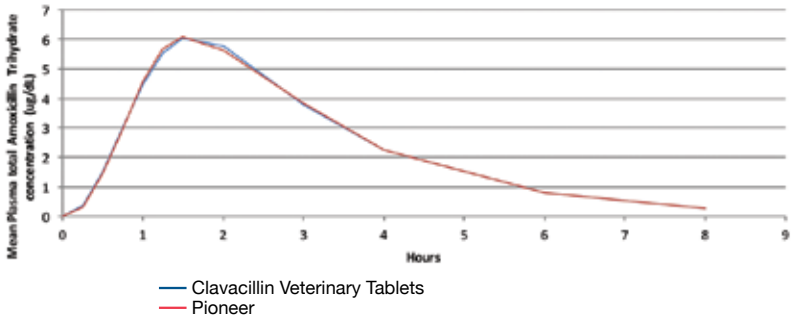
01PB-CLA50074-1218

BIOEQUIVALENCE DATA

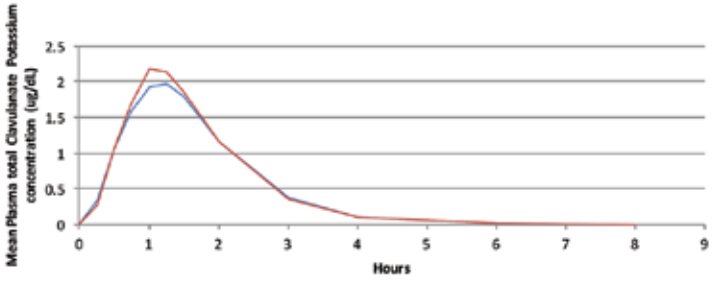
Bioequivalence Data: Clavacillin™ (amoxicillin trihydrate/clavulanate potassium) Veterinary Tablets vs. Pioneer

DOGS

Amoxicillin Trihydrate - Dog

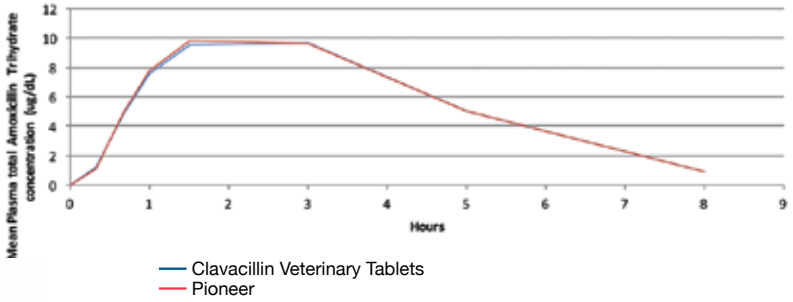


Clavulanate Potassium - Dog

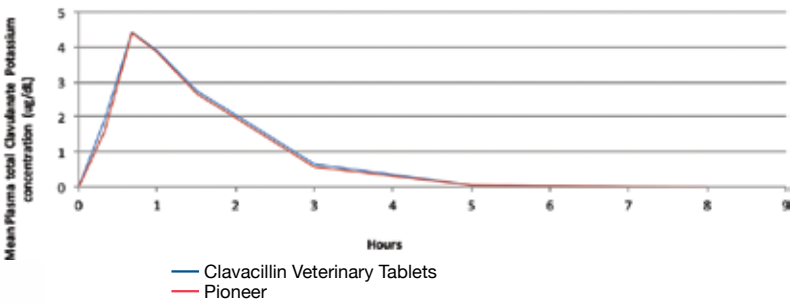


CATS

Amoxicillin Trihydrate - Cat



Clavulanate Potassium - Cat



DECHRA'S ADDITIONAL SYSTEMIC ANTIBIOTICS

What does bioequivalence mean?

Two drugs are considered to be bioequivalent when they are equally bioavailable, meaning equal in the rate and extent to which the active ingredient is absorbed and becomes available at the site of drug action.[1] The drugs must have the same strength, purity, and quality, and must be manufactured in FDA-inspected facilities.

How is bioequivalence assessed?

Bioequivalence is demonstrated through rigorously designed scientific studies in healthy animals. These studies determine the rate of absorption and extent of exposure for the active ingredients in both the generic and pioneer drugs; these parameters are determined through serial plasma drug measurements. The data for both drugs are then analyzed and must be comparable.

What does bioequivalence mean for me and my patients?

If two drugs are bioequivalent, you can expect the same safety and efficacy as the pioneer drug at a more affordable price. This is especially important for compliance in patients on long-term medications.

REFERENCE:

1. FDA Guidance for Industry: Bioequivalence guidance. http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052363.pdf (p 6). Accessed Oct., 2016.

Cefpoderm™

(cefpodoxime proxetil) Tablets

Available as 100 and 200 mg tablets (100 count bottles)

Enroquin™

Flavored Tablets (enrofloxacin)

Available in 22.7 mg tablets (100 and 500 count), 68 mg tablets (50 and 250 count), and 136 mg tablets (50 and 200 count)

Clavacillin™

(amoxicillin trihydrate/clavulanate potassium) Veterinary Tablets

For use in dogs and cats

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

DESCRIPTION:
Clavacillin (amoxicillin trihydrate/clavulanate potassium) is an orally administered formulation comprised of the broad-spectrum antibiotic amoxicillin trihydrate and the β-lactamase inhibitor, clavulanate 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, clavulanate potassium is potassium z-(3R,5R)-2-β-hydroxyethylidene clavam-3-carboxylate.

ACTIONS:
Clavacillin 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.
Clavacillin 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/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*[1], β-lactamase-producing *Staphylococcus aureus*[1] (penicillin resistant), *Staphylococcus* species[1], *Staphylococcus epidermidis*, *Staphylococcus intermedius*, *Streptococcus faecalis*, *Streptococcus* species[1], *Corynebacterium pyogenes*, *Corynebacterium* species, *Erysipelothrix rhusiopathiae*, *Bordetella bronchiseptica*, *Escherichia coli*[1], *Proteus mirabilis*, *Proteus* species, *Enterobacter* species, *Klebsiella pneumoniae*, *Salmonella dublin*, *Salmonella typhimurium*, *Pasteurella multocida*, *Pasteurella haemolytica*, *Pasteurella* species[1].

[1] 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.

SUSCEPTIBILITY TEST:
The recommended quantitative disc susceptibility method (FEDERAL REGISTER 37:20527-29; Bauer AW, Kirby WMM, Sherris JC, *et al*: Antibiotic susceptibility testing by standardized single disc method. *Am J Clin Path* 45:493, 1966) utilized 30 mcg Augmentin® (AMC) discs for estimating the susceptibility of bacteria to amoxicillin trihydrate and clavulanate potassium.

INDICATIONS:
Clavacillin 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. Amoxicillin trihydrate/clavulanate potassium 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 aureus*, non-β-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.
Therapy may be initiated with Clavacillin prior to obtaining results from bacteriological and susceptibility studies. A culture should be obtained prior to treatment to determine susceptibility of the organisms to Clavacillin. 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 at controlled room temperature, 68-77°F (20-25°C).
Do not remove from foil strip until ready to use.

ADVERSE REACTIONS:
Clavacillin 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 safety data sheet (SDS), contact Dechra at (866) 933-2472. 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 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.
Cats: The recommended dosage is 62.5 mg 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 3 days of treatment, therapy should be discontinued and the case reevaluated. Urinary tract infections may require treatment for 10-14 days or longer. The maximum duration of treatment should not exceed 30 days.

HOW SUPPLIED:
Clavacillin 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 62.5-mg tablet contains amoxicillin trihydrate equivalent to 50 mg of amoxicillin activity and 12.5 mg of clavulanic acid as the potassium salt (NDC 17033-440-21). 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 (NDC 17033-441-21). For use in dogs only.
Each 250-mg tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin activity and 50 mg of clavulanic acid as the potassium salt (NDC 17033-442-21). For use in dogs only.
Each 375-mg tablet contains amoxicillin trihydrate equivalent to 300 mg of amoxicillin activity and 75 mg of clavulanic acid as the potassium salt (NDC 17033-443-21). For use in dogs only.
Dispense according to recommendations outlined in Dosage and Administration section.

ANADA 200-592, Approved by FDA
Augmentin is a trademark owned by GlaxoSmithKline, LLC.

Manufactured for:
Dechra Veterinary Products
7015 College Boulevard, Suite 525
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Made In Austria.
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Veterinary Products