AMOXICILLIN AND CLAVULANATE POTASSIUM DROPS- amoxicillin and clavulanate potassium suspension
Cronus Pharma LLC

Amoxicillin and Clavulanate
Potassium for Oral Suspension
Drops

For veterinary oral suspension
For use in dogs and cats

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

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.

CLINICAL PHARMACOLOGY

Amoxicillin and Clavulanate Potassium for Oral Suspension 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.

Amoxicillin and Clavulanate Potassium for Oral Suspension 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*[1], *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 and clavulanate potassium tablets and amoxicillin and clavulanate potassium for oral suspension.

INDICATIONS AND USAGE

Amoxicillin and Clavulanate Potassium for Oral Suspension drops 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 and clavulanate potassium for oral suspension 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, Pasteurella multocida,* and *Pasteurella* spp.

Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

Therapy may be initiated with Amoxicillin and Clavulanate Potassium for Oral Suspension prior to obtaining results from bacteriological and susceptibility studies.

A culture should be obtained prior to treatment to determine susceptibility of the organisms to Amoxicillin and Clavulanate Potassium for Oral Suspension. 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. For use in dogs and cats only.

Keep Amoxicillin and Clavulanate Potassium for Oral Suspension in a secure location out of reach of dogs, cats and other animals to prevent accidental ingestion or overdose.

ADVERSE REACTIONS

Amoxicillin and Clavulanate Potassium for Oral Suspension 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 drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Cronus Pharma LLC at 1-844-227-6687. For additional information about adverse experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

DOSAGE AND ADMINISTRATION

Dogs: The recommended dosage is 6.25 mg/lb (1 mL/10 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 (1 mL) twice a day. Skin and soft tissue infections such as abscesses and cellulitis/dermatitis should be treated for 5–7 days or

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.

Reconstitution instructions - Oral Suspension
Add 14 mL of water to the 15-mL bottle and shake vigorously. Each mL of suspension will contain 50 mg of amoxicillin activity as the trihydrate and 12.5 mg of clavulanic acid activity as the potassium salt.

Note:
Any unused portion of the reconstituted suspension must be discarded after 10 days.

Refrigeration of the reconstituted suspension is required.

STORAGE CONDITIONS

Do not store dry powder at temperatures above 25°C (77°F).

HOW SUPPLIED

Amoxicillin and Clavulanate Potassium for Oral Suspension drops are supplied in 15-mL bottles containing 50 mg of amoxicillin/12.5 mg of clavulanic acid per mL.

Approved by FDA under ANADA # 200-709

Augmentin® is a trademark owned by
GlaxoSmithKline.

Manufactured for:
Cronus Pharma LLC,
East Brunswick, NJ 08816.
Contact No: 1-844-227-6687
(1-844-2-CRONUS)

Made in India
Revised: April 2021

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-024-11

Amoxicillin and Clavulanate Potassium for Oral Suspension

Drops

For veterinary oral suspension

For use in dogs and cats

When reconstituted each mL contains 50 mg of amoxicillin as the trihydrate and 12.5 of clavulanic acid as the potassium salt.

Do Not Use if Product is Discolored

Caution: Federal law resrticts this drug to use by or on the order of a licensed veterinarian.

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15 mL

AMOXICILLIN AND CLAVULANATE POTASSIUM DROPS

amoxicillin and clavulanate potassium suspension

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:69043-024
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMOXICILLIN ANHYDROUS (UNII: 9EM05410Q9) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	50 mg in 1 mL
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	12.5 mg in 1 mL

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69043-024-11	1 in 1 CARTON		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200709	09/25/2021	

Labeler - Cronus Pharma LLC (079421067)

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