

CLAVAMOX- amoxicillin and clavulanate potassium tablet, chewable
Zoetis Inc.

CLAVAMOX® CHEWABLE

CLAVAMOX® CHEWABLE
(amoxicillin and clavulanate potassium tablets)

Chewable Tablets

Antimicrobial For Oral Use In Dogs And Cats

CAUTION

CAUTION:

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

DESCRIPTION

CLAVAMOX CHEWABLE Tablet (amoxicillin and clavulanate potassium tablets) is an orally administered formulation comprised of the broad-spectrum antibiotic Amoxi® (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.

INDICATIONS

CLAVAMOX CHEWABLE 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 CHEWABLE 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 CLAVAMOX CHEWABLE 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.

DOSAGE AND ADMINISTRATION:

The dose should be prescribed using a combination of whole tablet strengths (62.5 mg, 125 mg, 250 mg, 375 mg). Do not remove from foil strip until ready to use. Even if the tablet is broken, the entire tablet should be consumed.

Dogs

The recommended dosage of CLAVAMOX CHEWABLE Tablet 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 of CLAVAMOX CHEWABLE Tablet 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.

CONTRAINDICATIONS

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

WARNINGS

Store CLAVAMOX CHEWABLE out of reach of dogs, cats, and other pets in a secured location in order to prevent accidental ingestion or overdose.

HUMAN WARNINGS: Not for human use. Keep this and all drugs out of reach of

children. Antimicrobial drugs, including penicillins and cephalosporins, can cause allergic reactions in sensitized individuals.

To minimize the possibility of allergic reactions, those handling such antimicrobials, including amoxicillin trihydrate/clavulanate potassium, are advised to avoid direct contact of the product with the skin and mucous membranes.

PRECAUTIONS

Prescribing antibacterial drugs in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant animal pathogens. Safety of use in pregnant or breeding animals has not been determined.

ADVERSE REACTIONS

CLAVAMOX CHEWABLE 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):

The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events reported for dogs and cats are listed in decreasing order of reporting frequency for CLAVAMOX: Anorexia, lethargy, vomiting and diarrhea.

For a copy of the Safety Data Sheet or to report adverse reactions, call Zoetis Inc. at 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

ACTIONS

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 CHEWABLE 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**, 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 hemolytica*, *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.

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 CLAVAMOX CHEWABLE Tablets.

PALATABILITY

The palatability of CLAVAMOX CHEWABLE Tablets was evaluated in a multi-location field trial. One hundred twelve (112) client-owned dogs were dosed with CLAVAMOX CHEWABLE Tablets at 6.25 mg/lb (12.5 mg/kg) twice daily for 7 days and evaluated for palatability of the product. Dogs freely consumed 83% of their doses within 5 minutes of offering from an empty bowl or owner's hand. Of the 17% of doses unconsumed after 5 minutes, 16% were administered with a treat/food or forced intake and 1% of doses were refused.

STORAGE INFORMATION

Store in a dry, cool place at temperatures not above 25°C (77°F). Do not remove from

foil strip until ready to use.

HOW SUPPLIED

CLAVAMOX CHEWABLE Tablets in the following strengths are supplied in single strip rolls containing 112 chewable tablets.

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. 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 50 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 75 mg of clavulanic acid as the potassium salt. For use in dogs only.

Dispense according to recommendations outlined in Dosage and Administration section.

Approved by FDA under NADA # 055-099

CLAVAMOX is a trademark owned by and used under license from GlaxoSmithKline. Augmentin is a trademark owned by GlaxoSmithKline.

Manufactured by:
Haupt Pharma, Latina, Italy

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Revised: September 2020

51745581

PRINCIPAL DISPLAY PANEL - 62.5 mg Tablet Carton

CLAVAMOX® CHEWABLE
(amoxicillin and clavulanate potassium tablets)
Antimicrobial For Oral Use In Dogs and Cats

62.5 MG CHEWABLE TABLETS

Net Contents: One single strip roll containing 112 chewable tablets

Dosage and Administration:
The dose should be prescribed using a combination of whole tablet strengths (62.5 mg, 125 mg, 250 mg, 375 mg). Do not remove from foil strip until ready to use. Even if the tablet is broken, the entire tablet should be consumed.

Dogs: 6.25 mg/lb of body weight twice a day.
Cats: 62.5 mg (1 tablet) twice a day.
If no response is seen after 5 days for dogs or 3 days for cats, discontinue treatment.
Do not exceed 30 days of therapy.

Warnings: Store CLAVAMOX CHEWABLE out of reach of dogs, cats, and other pets in a secured location in order to prevent accidental ingestion or overdose.

Before using this drug, read package insert for complete product information.

Store in a Dry, Cool Place at Temperatures Not Above 25°C (77°F)

Do Not Remove From Foil Strip Until Ready to Use
Read Insert for Complete Directions

CLAVAMOX® CHEWABLE zoetis
(amoxicillin and clavulanate potassium tablets)
Antimicrobial For Oral Use In Dogs And Cats

62.5 MG CHEWABLE TABLETS

Each chewable tablet contains amoxicillin trihydrate equivalent to 50 mg of amoxicillin activity and 12.5 mg of clavulanic acid as the potassium salt.

Approved by FDA under NADA # 055-099

Net Contents: One single strip roll containing 112 chewable tablets

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

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PRINCIPAL DISPLAY PANEL - 125 mg Tablet Carton

CLAVAMOX® CHEWABLE
(amoxicillin and clavulanate potassium tablets)
Antimicrobial For Oral Use In Dogs

125 MG CHEWABLE TABLETS

Net Contents: One single strip roll containing 112 chewable tablets

Dosage and Administration:
The dose should be prescribed using a combination of whole tablet strengths (62.5 mg, 125 mg, 250 mg, 375 mg). Do not remove from foil strip until ready to use. Even if the tablet is broken, the entire tablet should be consumed.

Dogs: 6.25 mg/lb of body weight twice a day.
If no response is seen after 5 days for dogs, discontinue treatment.
Do not exceed 30 days of therapy.

Warnings: Store CLAVAMOX CHEWABLE out of reach of dogs, cats, and other pets in a secured location in order to prevent accidental ingestion or overdose.

Before using this drug, read package insert for complete product information.

Store in a Dry, Cool Place at Temperatures Not Above 25°C (77°F)

Do Not Remove From Foil Strip Until Ready to Use
Read Insert for Complete Directions

CLAVAMOX® CHEWABLE zoetis
(amoxicillin and clavulanate potassium tablets)
Antimicrobial For Oral Use In Dogs

125 MG CHEWABLE TABLETS

Each chewable tablet contains amoxicillin trihydrate equivalent to 100 mg of amoxicillin activity and 25 mg of clavulanic acid as the potassium salt.

Net Contents: One single strip roll containing 112 chewable tablets

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

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PRINCIPAL DISPLAY PANEL - 250 mg Tablet Carton

CLAVAMOX[®] CHEWABLE

(amoxicillin and clavulanate potassium tablets)

Antimicrobial For Oral Use In Dogs

250 MG CHEWABLE TABLETS

Net Contents: One single strip roll containing 112 chewable tablets

Dosage and Administration:

The dose should be prescribed using a combination of whole tablet strengths (62.5 mg, 125 mg, 250 mg, 375 mg). Do not remove from foil strip until ready to use. Even if the tablet is broken, the entire tablet should be consumed.

Dogs: 6.25 mg/lb of body weight twice a day.

If no response is seen after 5 days for dogs, discontinue treatment. Do not exceed 30 days of therapy.

Warnings:

Store CLAVAMOX CHEWABLE out of reach of dogs, cats, and other pets in a secured location in order to prevent accidental ingestion or overdose.

Before using this drug, read package insert for complete product information.

Store in a Dry, Cool Place at Temperatures Not Above 25°C (77°F)

Do Not Remove From Foil Strip Until Ready to Use
Read Insert for Complete Directions

CLAVAMOX[®] CHEWABLE

(amoxicillin and clavulanate potassium tablets)

zoetis

Antimicrobial For Oral Use In Dogs

250 MG CHEWABLE TABLETS

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

Net Contents: One single strip roll containing 112 chewable tablets

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

Approved by FDA under NADA # 055-099

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PRINCIPAL DISPLAY PANEL - 375 mg Tablet Carton

CLAVAMOX[®] CHEWABLE

(amoxicillin and clavulanate potassium tablets)

Antimicrobial For Oral Use In Dogs

375 MG CHEWABLE TABLETS

Net Contents: One single strip roll containing 112 chewable tablets

Dosage and Administration:

The dose should be prescribed using a combination of whole tablet strengths (62.5 mg, 125 mg, 250 mg, 375 mg). Do not remove from foil strip until ready to use. Even if the tablet is broken, the entire tablet should be consumed.

Dogs: 6.25 mg/lb of body weight twice a day.

If no response is seen after 5 days for dogs, discontinue treatment. Do not exceed 30 days of therapy.

Warnings: Store CLAVAMOX CHEWABLE out of reach of dogs, cats, and other pets in a secured location in order to prevent accidental ingestion or overdose.

Before using this drug, read package insert for complete product information.

Store in a Dry, Cool Place at Temperatures Not Above 25°C (77°F)

Do Not Remove From Foil Strip Until Ready to Use
Read Insert for Complete Directions

zoetis

CLAVAMOX[®] CHEWABLE

(amoxicillin and clavulanate potassium tablets)

zoetis

Antimicrobial For Oral Use In Dogs

375 MG CHEWABLE TABLETS

Each chewable tablet contains amoxicillin trihydrate equivalent to 300 mg of amoxicillin activity and 75 mg of clavulanic acid as the potassium salt.

Net Contents: One single strip roll containing 112 chewable tablets

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

Approved by FDA under NADA # 055-099

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CLAVAMOX

amoxicillin and clavulanate potassium tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-1023
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
(2S,5R,6R)-6-((R)-(-)-2-AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCL(3.2.0)HEPTANE-2-CARBOXYLIC ACID TRIHYDRATE (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	50 mg
CLAVULANATE POTASSIUM (UNII: Q420MW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	12.5 mg

Product Characteristics

Color	brown (mottled)	Score	2 pieces
Shape	SQUARE	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1023-1	10 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:54771-1023-2	1 in 1 CARTON		
2		112 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA055099	05/24/2017	

CLAVAMOX

amoxicillin and clavulanate potassium tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-1020
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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(2S,5R,6R)-6-((R)-(-)-2-AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCL(3.2.0)HEPTANE-2-CARBOXYLIC ACID TRIHYDRATE (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	100 mg
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	25 mg

Product Characteristics

Color	brown (mottled)	Score	2 pieces
Shape	SQUARE	Size	11mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1020-1	10 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:54771-1020-2	1 in 1 CARTON		
2		112 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA055099	05/24/2017	

CLAVAMOX

amoxicillin and clavulanate potassium tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-1021
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
(2S,5R,6R)-6-((R)-(-)-2-AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCL(3.2.0)HEPTANE-2-CARBOXYLIC ACID TRIHYDRATE (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	200 mg
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	50 mg

Product Characteristics

Color	brown (mottled)	Score	2 pieces
Shape	SQUARE	Size	15mm

Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1021-1	10 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:54771-1021-2	1 in 1 CARTON		
2		112 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA055099	05/24/2017		

CLAVAMOX

amoxicillin and clavulanate potassium tablet, chewable

Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-1022	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
(2S,5R,6R)-6-((R)-(-)-2-AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCL(3.2.0)HEPTANE-2-CARBOXYLIC ACID TRIHYDRATE (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	300 mg		
CLAVULANATE POTASSIUM (UNII: Q420MW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	75 mg		
Product Characteristics				
Color	brown (mottled)	Score	2 pieces	
Shape	SQUARE	Size	18mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1022-1	10 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:54771-1022-2	1 in 1 CARTON		

2	112 in 1 BLISTER PACK		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA055099	05/24/2017	

Labeler - Zoetis Inc. (828851555)

Revised: 7/2021

Zoetis Inc.