Kesium® (amoxicillin and clavulanate potassium tablets)

The 1st chewable tablet bioequivalent to Clavamox® Chewable Tablets (amoxicillin and clavulanate potassium tablets)

Kesium® Chewable Tablets offers the same trusted efficacy and safety profile with convenient dosing options at an affordable price.

MWI Item #	126035	126036	126038	126037
Strength	62.5 mg	125 mg	250 mg	375 mg
Tablets per box	100	100	96	96
Standard Vet Price	$34.72	$64.24	$101.90	$144.76

Treat Bacterial Infections

Kesium® can be used to treat various dermatological, soft tissue, and periodontal infections for dogs as well as dermatological, soft tissue, and urinary tract infections for cats. The combination of amoxicillin and clavulanate potassium is rapidly absorbed to treat bacterial infections. Please see our product insert for a full list of susceptible strains of organisms.

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

Periodontal Infections

Treat canine periodontal disease caused by susceptible strains of aerobic and anaerobic bacteria.

Skin and Soft Tissue Infections

Treat wounds, abscesses, and cellulitis in dogs and cats; superficial and deep pyoderma in dogs; and dermatitis in cats—all due to susceptible strains of bacteria.

Urinary Tract Infections

Treat cystitis caused by susceptible strains of E. coli in cats.

In a study conducted with Cats, Kesium was accepted in 74% of instances.*

Convenient Dosing Options

Kesium® is a pork-flavored, chewable tablet to make administration easy for pet owners. The chewable tablets are available in four strengths: 62.5 mg for Dogs & Cats, and 125 mg, 250 mg, and 375 mg for Dogs.

Actual Size (62.5 mg)

Cats	10 lb Dog	20 lb Dog	40 lb Dog	60 lb Dog	80 lb Dog	100 lb Dog
1 - **62.5 mg Chewable**	1 - **62.5 mg Chewable**	1 - **125 mg Chewable**	1 - **250 mg Chewable**	1 - **375 mg Chewable**	2 - **250 mg Chewables**	1 - **250 mg Chewable** + 1 - **375 mg Chewable**
						

IMPORTANT SAFETY INFORMATION: Kesium® Chewable Tablets contain a semisynthetic penicillin (amoxicillin) and have the potential for producing allergic reactions. People with known hypersensitivity to penicillin or cephalosporins should avoid exposure to Kesium® Chewable Tablets. Do not use 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 product insert for complete details.

*Laboratory study. Data on file.

KSM-100-25v3

Kesium®

(amoxicillin and clavulanate potassium tablets)

Chewable Tablets

Antimicrobial For Oral Use In Dogs and Cats

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

DESCRIPTION: Kesium Chewable Tablet (amoxicillin and clavulanate potassium tablets) 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.

INDICATIONS: Kesium 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. Kesium 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 Kesium prior to obtaining results from bacteriological and susceptibility studies. A culture should be obtained prior to treatment to determine susceptibility of the organisms to Kesium. 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 blister until ready to use. Pierce the foil blister cavity to access the tablet. Even if the tablet is broken, the entire tablet should be consumed.

Dogs: The recommended dosage of Kesium 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 Kesium 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 Kesium 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 and 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: Kesium 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 amoxicillin and clavulanate potassium: Anorexia, lethargy, vomiting and diarrhea.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Ceva Animal Health, LLC at 1-800-999-0297. 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.

Kesium 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, Pasteurell*a 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 amoxicillin and clavulanate potassium tablets.

STORAGE INFORMATION: Do not store above 25°C (77°F). Do not remove from foil blister until ready to use.

HOW SUPPLIED: Kesium Chewable Tablets in the following strengths of 62.5 mg, 125 mg, 250 mg and 375 mg are supplied in foil blister cards. Each carton of 62.5 mg and 125 mg strength holds 10 blister cards with10 tablets (100 tablets per carton). Each carton of 250 mg and 375 mg strength holds 12 blister cards with 8 tablets (96 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. 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 ANADA # 200-749

Marketed by: Ceva Animal Health, LLC, Lenexa, KS 66215

Made in Germany

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