



CLAVAMOX[®] is an antibiotic used for the treatment of skin and soft tissue infections in dogs and cats, for periodontal infections in dogs, and for urinary tract infections in cats
(amoxicillin trihydrate/
clavulanate potassium)



: KNOW THE FACTS

Be sure to read this booklet before your dog or cat receives Clavamox[®]. You should also review it each time your pet receives a prescription for this treatment.

This booklet is only a summary. It does not replace what your veterinarian has told you. To learn more about Clavamox[®], talk to your veterinarian.

: WHAT IS CLAVAMOX[®] ?

Clavamox[®] is an antibiotic belonging to the penicillin family. Clavamox[®] contains amoxicillin and clavulanate and is known as potentiated penicillin. Antibiotics, also known as antimicrobials, are used to treat infections caused by bacteria. They do not work against viruses.

Clavamox[®] has been shown to be effective in the treatment of skin and soft tissue infections in dogs and cats, periodontal (tooth related) infections in dogs and urinary tract (bladder and kidney) infections in cats.

: HOW DOES CLAVAMOX[®] WORK?

There are many kinds of bacteria which may affect different parts of the body. Some cause infections of the skin like ear infections, raw bleeding areas called “hot spots,” wounds, and pus-filled abscesses. Others cause periodontal (tooth related) infections, while others cause urinary tract (bladder and kidneys) infections or other problems.

There are also many kinds of antibiotics. Each one has a special way of fighting bacteria. Some stop bacteria from growing so the animal’s immune system can kill them. Others kill the bacteria directly. Either way, antibiotics work with your pet’s body to clear the infection.

Each antibiotic works only against certain bacteria. It may not work against others. To treat your pet’s infection, you need the right kind of antibiotic.

Clavamox[®] kills bacteria directly.

: WHEN SHOULD CLAVAMOX[®] BE USED IN PETS?

Sometimes dogs and cats get infections on the surface of their skin, in wounds, or in cuts. Left untreated, these can affect your pet’s overall health. Infections on the skin may cause severe pain, loss of hair, itching, and/or a bad odor. In addition to the pain, if the infection is in a wound, it might slow the healing. If the infected wound is on a leg, you may see your pet start to limp. Clavamox[®] is used to treat many of these infections in dogs and cats.

Pets sometimes get infections around their teeth and gums (periodontal infections) as well. Left untreated, these may progress to mouth pain, difficulty in eating, bad breath, and tooth loss. Clavamox[®] can be used to treat periodontal infections in dogs.

CLAVAMOX® :

Pets can also get infections in their urinary tract (bladder and kidneys). These can cause pain or make your pet feel as if it needs to urinate more often. Other common signs are accidents in the house and blood in the urine. Left untreated, these can cause kidney damage and result in your pet becoming very sick. Clavamox® can be used to treat urinary tract infections in cats.

: HOW DO VETERINARIANS KNOW WHICH ANTIBIOTIC TO USE?

Veterinarians make this choice based on what they see and know about your pet's health. This choice may be based on many things, such as:

- Examination of your pet
- The body part of your pet that is affected
- The kind of bacteria that is causing the infection
- How difficult it is for you to give your pet an antibiotic

Sometimes your veterinarian may want to take a sample of bacteria from the infection for a culture and sensitivity test. Your veterinarian will recommend this test to help him or her decide which antibiotic to use. The test can be very useful to identify hard-to-treat infections.

: WILL CLAVAMOX® HELP MY PET?

Most pets given this treatment will respond well. Most signs of the infection start to go away within three days. If they do not, your pet may:

- Have more than one kind of bacterial infection
- Have an infection caused by something other than bacteria
- Be stressed or have other diseases that weaken the body's ability to help fight off the infection
- Need a different antibiotic, because the bacteria causing the infection are not bacteria that Clavamox® works against

If your pet doesn't seem to be getting better, contact your veterinarian. Your veterinarian may do some extra tests. The kind of antibiotic your pet is taking may also be changed.

: IS THERE ANY FOLLOW-UP OR MONITORING I SHOULD DO?

You may be asked to bring your pet back at some point during or after treatment. This will depend on:

- What kind of infection your pet has
- How sick your pet is
- If your pet had this infection before

Be sure to follow your veterinarian's advice. Having your pet checked again may improve its chances of getting well. If you do not follow your veterinarian's recommendation for a recheck it may also make the infection harder to treat and more costly.

: HOW IS CLAVAMOX® GIVEN TO MY PET?

Antibiotics must be prescribed by a veterinarian and should not be available to you in any other way. Clavamox® is available in either pill or liquid form.

At home, you can give the Clavamox® pills or liquid to your pet by mouth. Your veterinarian will tell you how and when to do this. Clavamox® is given twice a day to both dogs and cats.

Always follow the directions and give this treatment the right way. This can help your pet get better more quickly and stay healthy longer. If you do not understand the directions, call your veterinarian.

: HOW LONG DO I HAVE TO GIVE MY PET CLAVAMOX®?

You should give Clavamox® for as long as your veterinarian told you to give it.

Some pet owners are tempted to stop treatment when their pet is feeling better. This is not a good idea and can be very

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harmful in the long run. It should be done only if your veterinarian says so. Even though your pet may seem better, the infection may still be there. So if you stop treating your pet too soon, the infection can come back. It can also be much harder to control.

Shortening the use of these treatments or skipping doses can lead to the growth of resistant bacteria. This kind of bacteria may be bad for your pet as well as other pets and people. So be sure to give all of the treatment as exactly as your veterinarian recommended.

If you have trouble giving the treatment to your pet, ask your veterinarian for help.

: DOES CLAVAMOX® HAVE SIDE EFFECTS?

As with any medicine, Clavamox® may cause problems. Some pets may have an allergic reaction to this kind of medicine. Symptoms of an allergic reaction include swelling of the face, itchy skin, hives, vomiting, diarrhea or breathing problems. Allergic reactions may be serious, and may happen very quickly. If you think your pet is having an allergic reaction to the medicine, call your veterinarian right away. These kinds of problems must be treated quickly.

Penicillins may cause loss of appetite, vomiting or diarrhea¹. Since Clavamox contains amoxicillin, which is a member of the penicillin family, this may be a concern while your pet is taking Clavamox. Be sure to contact your veterinarian if your pet has any stomach problems while on treatment with Clavamox.

Call your veterinarian if you notice any changes in your pet while taking Clavamox®.

: SHOULD SOME PETS NOT GET CLAVAMOX®?

Clavamox® should not be given to pets that have had a previous history of allergic reactions to Clavamox® or other medicines like Clavamox® including penicillins or cephalosporins. Talk to your veterinarian if you are unsure about your pet's history with these kinds of medicines.

: WHAT ELSE SHOULD I KNOW ABOUT CLAVAMOX®?

Tell your veterinarian if your pet is pregnant or nursing, or if you plan to breed your pet soon. Clavamox® has not been tested in pets that are pregnant or used for breeding.

: HOW SHOULD CLAVAMOX® BE STORED?

- Clavamox® tablets should be kept in a cool dry place at room temperature. (Do not remove the tablets from the foil strip until ready to use.)
- Clavamox® drops should be kept in the refrigerator. They are good for 10 days after you have mixed up the solution. After that, be sure to throw away any unused drops.

: NOTE:

- Clavamox® is for dogs and cats only
- Clavamox® must be prescribed by a veterinarian
- Keep out of reach of children

1. Plumb, DC. 2005. Amoxicillin, p. 42. In Plumb DC (ed), Plumb's Veterinary Drug Handbook. Blackwell Publishing, Ames, IA

Clavamox®

(amoxicillin/clavulanic acid)

CAUTION

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

DESCRIPTION

CLAVAMOX (amoxicillin trihydrate/clavulanate potassium) 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(-)-a-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-b-hydroxyethylidene clavam-3-carboxylate.

ACTIONS

CLAVAMOX 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.

CLAVAMOX 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 haemolytica*, *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 Tablets and Drops.

INDICATIONS

CLAVAMOX Tablets and 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. CLAVAMOX 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 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.

CONTRAINDICATIONS

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

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.

WARNINGS

Safety of use in pregnant or breeding animals has not been determined.

CLAVAMOX Tablets should be stored in a dry, cool place at temperatures not above 25°C (77°F). Do not remove from foil strip until ready to use.

DOSAGE AND ADMINISTRATION

Dosage and Directions for Use of CLAVAMOX Tablets and CLAVAMOX Drops:

Dogs

The recommended dosage for CLAVAMOX Tablets is 6.25 mg/lb of body weight twice a day. The recommended dosage for CLAVAMOX Drops 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 for CLAVAMOX Tablets is 62.5 mg twice a day. The recommended dosage for CLAVAMOX Drops 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 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.

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.

HOW SUPPLIED

CLAVAMOX Drops are supplied in: 15-mL bottle—50 mg amoxicillin/12.5 mg clavulanic acid per mL.

CLAVAMOX Tablets, in the following strengths, are supplied in strip packs. Each container holds 15 strips with 14 tablets per strip (210 tablets per container).

62.5 mg tablet—dogs and cats. 125 mg tablet—dogs only. 250 mg tablet—dogs only. 375 mg tablet—dogs only.

Dispense according to recommendations outlined in Dosage and Administration section.

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For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Pfizer Animal Health at 1-800-366-5288.

NADA #55-099, NADA #55-101, Approved by FDA

