BIOMOX- amoxicillin suspension Virbac AH, Inc.

Approved by FDA under NADA # 065-495 BIOMOX® (amoxicillin)

Veterinary For Oral Suspension For use in DOGS only.

DESCRIPTION

BIOMOX® (amoxicillin) is a broad-spectrum, semisynthetic antibiotic which provides bactericidal activity against a wide range of common gram-positive and gram-negative pathogens. Amoxicillin chemically is $D-(-)\alpha$ -amino-p-hydroxybenzyl penicillin trihydrate.

Inactive Ingredients

Cherry Flavor, Silicon Dioxide NF, FD&C Red #40, Polyoxyethylene-Polyoxypropylene Glycol, Sodium Benozate, Sodium Citrate, Sodium Saccharin, and Sucrose

ACTION

Amoxicillin has bactericidal activity against susceptible organisms similar to that of ampicillin. It acts by inhibiting the biosynthesis of bacterial wall mucopeptides. Most strains of the following gram-positive and gramnegative bacteria have demonstrated susceptibility to: amoxicillin, both *in vitro* and *in vivo*: nonpenicillinase-producing staphylococci, alpha- and betahemolytic streptococci, *Streptococcus faecalis, Escherichia coli* and *Proteus mirabilis*. Amoxicillin does not resist destruction by penicillinase; therefore, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. Most strains of Enterobacter and klebsiella and all strains of Pseudomonas are resistant.

Amoxicillin may be given without regard to meals because it is stable in gastric acid. It is rapidly absorbed following oral administration and diffuses readily into most body fluids and tissues. It diffuses poorly into the brain and spinal fluid except when the meninges are inflamed. Most of the amoxicillin is excreted in the urine unchanged.

INDICATIONS

BIOMOX® (amoxicillin) for oral suspension is indicated in the treatment of the following infections in dogs when caused by susceptible strains of organisms:

BACTERIAL DERMATITIS due to *Staphylococcus aureus, Streptococcus spp.; Staphylococcus spp.;* and *E. coli.*

SOFT TISSUE INFECTIONS (abscesses, wounds, lacerations) due to *Staphylococcus* aureus, *Streptococcus spp.; E. coli, Proteus mirabilis* and *Staphylococcus spp.*

As is true with all antibiotic therapy, appropriate *in vitro* cultures and sensitivities should be conducted prior to treatment.

CONTRAINDICATIONS

Use of amoxicillin is contraindicated in animals with a history of an allergic reaction to penicillin.

ADVERSE REACTIONS

Amoxicillin is a semisynthetic penicillin and, therefore, has the potential for producing allergic reactions. Epinephrine and/or steroids should be administered if an allergic reaction occurs.

WARNINGS

For use in dogs only.

PRECAUTIONS

Until adequate reproductive studies are accomplished, Biomox (amoxicillin) for oral suspension should not be used in pregnant or breeding animals.

CAUTION

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

DOSAGE AND ADMINISTRATION

The recommended dosage is 5 mg per pound of body weight administered twice daily for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvment is noted in 5 days, the diagnosis should be reconsidered and therapy changed.

DIRECTIONS FOR MIXING ORAL SUSPENSION

Add sufficient water to the bottle as indicated in the table below and shake vigorously. Each mL of suspension will contain 50 mg of amoxicillin as the trihydrate.

Amount of Mator

Bottle Size	to Add for Reconstitution		
15 mL	11 mL		
30 mL	21 mL		

Note: When stored at room temperature or in refrigerator, discard unused portion of reconstituted suspension after 14 days.

SUPPLY

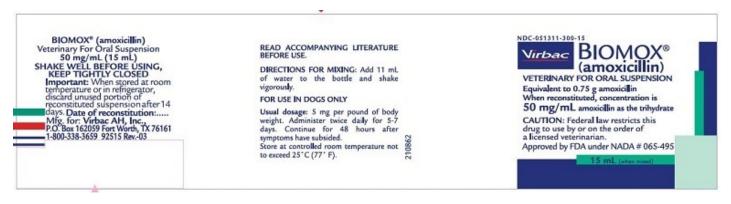
Bimox® (amoxicillin) for oral suspension is supplied in bottles containing 0.75 g of amoxicillin activity in bottles of 15 mL or 1.5 g of amoxicillin activity in bottles of 30 mL. After reconstitution with the required amount of water, each mL will contain 50 mg of amoxicillin as the trihydrate.

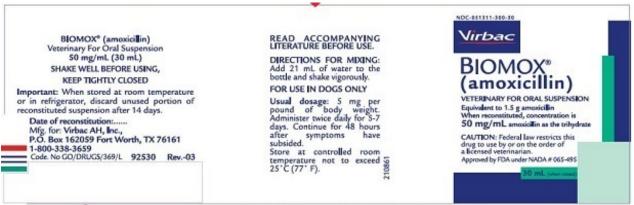
Manufactured for:

Virbac AH, Inc.

P.O. Box 162059 Fort Worth, TX 76161 1-800-338-3659

92515 07/19 Rev.-03





BIOMOX amoxicillin suspension Product Information Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:51311-300 Route of Administration ORAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
amoxicillin (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	0.75 g in 15 mL

Product Characteristics			
Color	white (off-white to pinkish)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-300-15	15 mL in 1 BOTTLE, DROPPER		
2	NDC:51311-300-30	30 mL in 1 BOTTLE, DROPPER		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA065495	05/24/2010		

Labeler - Virbac AH, Inc. (131568396)

Establishment				
Name	Address	ID/FEI	Business Operations	
Medispray Laboratories Private Ltd		915793457	manufacture	

Establishment				
Name	Address	ID/FEI	Business Operations	
Centrient Pharmaceuticals Netherlands		860184986	api manufacture	

Establishment				
Name	Address	ID/FEI	Business Operations	
Alcami Missouri Corporation		117877975	analysis	

Establishment			
Name	Address	ID/FEI	Business Operations
Alcami Carolinas Corporation		831351445	analysis

Revised: 1/2022 Virbac AH, Inc.