BIOMOX- amoxicillin suspension
Virbac AH, Inc.

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-(-)a-amino-p-hydroxybenzyl penicillin trihydrate.

Inactive Ingredients

Cherry Flavor, Silicon Dioxide NF, FD&C Red #40, Polyoxyethylene-Polyoxypropylene Glycol, Sodium Benzoate, 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 gram-negative bacteria have demonstrated susceptibility to amoxicillin, both *in vitro* and *in vivo:* nonpenicillinase-producing staphylococci, alpha- and beta-hemolytic 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 improvement 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.

Bottle Size	Amount of Water 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

Biomox® (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

05/08

Rev.-02

PRINCIPAL DISPLAY PANEL - 15 mL Powder Bottle

NDC-051311-300-15

Virbac
ANIMAL HEALTH

BIOMOX®
(amoxicillin)

VETERINARY FOR ORAL SUSPENSION

Equivalent to 0.75 g amoxicillin
When reconstituted, concentration is
50 mg/mL amoxicillin as the trihydrate

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

NADA # 65-495, Approved by FDA

15 mL (when mixed)

PRINCIPAL DISPLAY PANEL - 30 mL Powder Bottle

NDC-051311-300-30

Virbac
ANIMAL HEALTH

BIOMOX®
(amoxicillin)

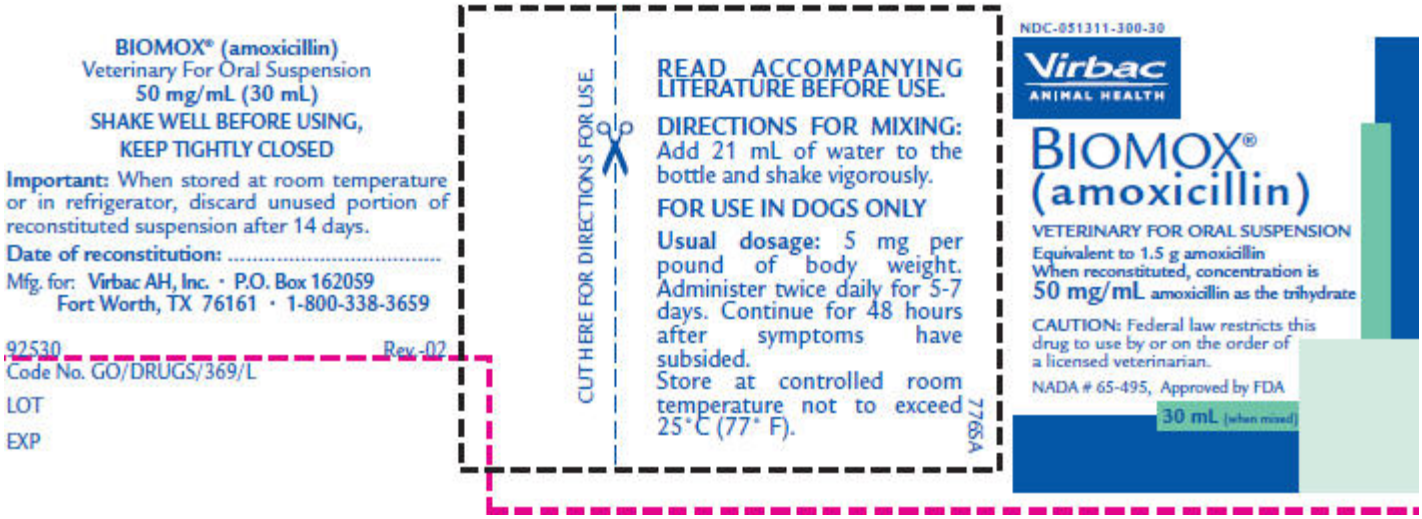
VETERINARY FOR ORAL SUSPENSION

Equivalent to 1.5 g amoxicillin
When reconstituted, concentration is
50 mg/mL amoxicillin as the trihydrate

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

NADA # 65-495, Approved by FDA

30 mL (when mixed)



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			

Packaging

#	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
Teva Pharmaceutical USA, Inc.		611568031	api manufacture

Revised: 7/2017 Virbac AH, Inc.