

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-(-)-α-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 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 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.

<u>Bottle Size</u>	<u>Amount of Water to Add for Reconstitution</u>
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)
Veterinary For Oral Suspension
50 mg/mL (15 mL)
**SHAKE WELL BEFORE USING,
KEEP TIGHTLY CLOSED**
Important: When stored at room
temperature or in refrigerator,
discard unused portion of
reconstituted suspension after 14
days. **Date of reconstitution:.....**
Mfg. for: Virbac AH, Inc.,
P.O. Box 162059 Fort Worth, TX 76161
1-800-338-3659 92515 Rev.-03

**READ ACCOMPANYING LITERATURE
BEFORE USE.**
DIRECTIONS FOR MIXING: Add 11 mL
of water to the bottle and shake
vigorously.
FOR USE IN DOGS ONLY
Usual dosage: 5 mg per pound of body
weight. Administer twice daily for 5-7
days. Continue for 48 hours after
symptoms have subsided.
Store at controlled room temperature not
to exceed 25° C (77° F).

NDC-051311-300-15
Virbac **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.
Approved by FDA under NADA # 065-495
15 mL (when mixed)

BIOMOX® (amoxicillin)
Veterinary For Oral Suspension
50 mg/mL (30 mL)
**SHAKE WELL BEFORE USING,
KEEP TIGHTLY CLOSED**
Important: When stored at room temperature
or in refrigerator, discard unused portion of
reconstituted suspension after 14 days.
Date of reconstitution:.....
Mfg. for: Virbac AH, Inc.,
P.O. Box 162059 Fort Worth, TX 76161
1-800-338-3659
Code: No GO/DRUGS/369/L 92530 Rev.-03

**READ ACCOMPANYING LITERATURE
BEFORE USE.**
DIRECTIONS FOR MIXING:
Add 21 mL of water to the
bottle and shake vigorously.
FOR USE IN DOGS ONLY
Usual dosage: 5 mg per
pound of body weight.
Administer twice daily for 5-7
days. Continue for 48 hours
after symptoms have
subsided.
Store at controlled room
temperature not to exceed
25° C (77° F).

NDC-051311-300-30
Virbac **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.
Approved by FDA under NADA # 065-495
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
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