

**BIOMOX- amoxicillin tablet**  
**Virbac AH, Inc.**

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**Approved by FDA under NADA # 065-492**  
**BIOMOX®**  
**(amoxicillin tablets)**

For use in DOGS only.

**DESCRIPTION**

BIOMOX® (amoxicillin tablets) are 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**

Dibasic Calcium Phosphate Dihydrate, Magnesium Stearate, Microcrystalline Cellulose and Sodium Starch Glycolate.

**ACTION**

Amoxicillin has bactericidal activity against susceptible organisms similar to that of ampicillin. It acts by inhibiting the biosynthesis of bacterial cell 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, *Enterococcus 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 tablets) are indicated for 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 *Escherichia coli*.

**SOFT TISSUE INFECTIONS**

(abscesses, wounds, lacerations) due to *Staphylococcus aureus*, *Enterococcus faecalis*, *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus spp.*

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 tablets) 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 or 48 hours after all symptoms have subsided. If no improvement is noted in 5 days, the diagnosis should be reconsidered and therapy changed.

## **SUPPLY**

Biomox® (amoxicillin tablets) are supplied in 50 mg, 100 mg and 200 mg concentrations in bottles of 500 tablets.

Manufactured for:

**Virbac AH, Inc.**

P.O. Box 162059

Fort Worth, TX 76161

1-800-338-3659

Printed in USA Rev. -06 05/19

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**Bulk Container –**  
Not For Household Dispensing.  
Store at controlled room temperature between 15°C and 30°C (59°F and 86°F).

Mfg. for: Virbac AH, Inc. 302012  
P.O. Box 162059 Rev. -04  
Fort Worth, TX 76161 09/18  
1-800-338-3659  
Made in India  
Code No. GO/DRUGS/369/L 214636

8 14514 02505 9

**Virbac**  
NDC-051311-201-50  
**BIOMOX®**  
(amoxicillin tablets)  
**50 mg**

Each tablet contains amoxicillin trihydrate equivalent to 50 mg of amoxicillin.  
**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA # 65-492, Approved by FDA  
500 Tablets

**READ ACCOMPANYING LITERATURE BEFORE USE.**  
For use in DOGS only.  
**Recommended Dosage:**  
5 mg per pound of body weight twice a day.  
Dosage should be continued for 5 - 7 days or 48 hours after all symptoms have subsided.

51 mm

Accordian Label (Insert)

**READ ACCOMPANYING LITERATURE BEFORE USE.**  
For use in DOGS only.  
**Recommended Dosage:**  
5 mg per pound of body weight twice a day.  
Dosage should be continued for 5 - 7 days or 48 hours after all symptoms have subsided.

CUT HERE FOR DIRECTIONS FOR USE.

214636

**Bulk Container –**  
Not For Household Dispensing.  
Store at controlled room temperature between 15°C and 30°C (59°F and 86°F).

Mfg. for: Virbac AH, Inc. 302013  
P.O. Box 162059 Rev. -04  
Fort Worth, TX 76161 09/18  
1-800-338-3659  
Made in India  
Code No. GO/DRUGS/369/L 214637

8 14514 02105 1

**Virbac**  
NDC-051311-203-50  
**BIOMOX®**  
(amoxicillin tablets)  
**100 mg**

Each tablet contains amoxicillin trihydrate equivalent to 100 mg of amoxicillin.  
**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA # 65-492, Approved by FDA  
500 Tablets

**READ ACCOMPANYING LITERATURE BEFORE USE.**  
For use in DOGS only.  
**Recommended Dosage:**  
5 mg per pound of body weight twice a day.  
Dosage should be continued for 5 - 7 days or 48 hours after all symptoms have subsided.

51 mm

Accordian Label (Insert)

**READ ACCOMPANYING LITERATURE BEFORE USE.**  
For use in DOGS only.  
**Recommended Dosage:**  
5 mg per pound of body weight twice a day.  
Dosage should be continued for 5 - 7 days or 48 hours after all symptoms have subsided.

CUT HERE FOR DIRECTIONS FOR USE.

214637

**Bulk Container –**  
Not For Household Dispensing.  
Store at controlled room temperature between 15°C and 30°C (59°F and 86°F).

Mfg. for: Virbac AH, Inc. 302014  
P.O. Box 162059 Rev. -04  
Fort Worth, TX 76161 09/18  
1-800-338-3659  
Made in India  
Code No. GO/DRUGS/369/L 214678

8 14514 02205 8

**Virbac**  
NDC-051311-205-50  
**BIOMOX®**  
(amoxicillin tablets)  
**200 mg**

Each tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin.  
**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA # 65-492, Approved by FDA  
500 Tablets

**READ ACCOMPANYING LITERATURE BEFORE USE.**  
For use in DOGS only.  
**Recommended Dosage:**  
5 mg per pound of body weight twice a day.  
Dosage should be continued for 5 - 7 days or 48 hours after all symptoms have subsided.

76 mm

Accordian Label (Insert)

**READ ACCOMPANYING LITERATURE BEFORE USE.**  
For use in DOGS only.  
**Recommended Dosage:**  
5 mg per pound of body weight twice a day.  
Dosage should be continued for 5 - 7 days or 48 hours after all symptoms have subsided.

CUT HERE FOR DIRECTIONS FOR USE.

214678

**BIOMOX**  
amoxicillin tablet

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-201
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
amoxicillin (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	50 mg	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-201-50	500 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA065492	05/24/2010	

## BIOMOX

amoxicillin tablet

### Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-203
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
amoxicillin (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	100 mg

### Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-203-50	500 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA065492	05/24/2010	

## BIOMOX

amoxicillin tablet

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:51311-205
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
amoxicillin (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	200 mg

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-205-50	500 in 1 BOTTLE		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NADA	NADA065492	05/24/2010	

**Labeler** - Virbac AH, Inc. (131568396)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Medispray Laboratories Private Ltd		915793457	manufacture

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Centrient Pharmaceuticals Netherlands		860184986	api manufacture

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Alcami Missouri Corporation		117877975	analysis

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Alcami Carolinas Corporation		831351445	analysis

Revised: 1/2022

Virbac AH, Inc.