

NADA # 65-495, Approved by FDA

BIOMOX® (amoxicillin)

Veterinary For Oral Suspension
For use in DOGS only.

DESCRIPTION: BIOMOX® (amoxicillin) is a broad-spectrum, semi-synthetic antibiotic which provides bacterial 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 it 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

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

NADA # 65-495, Approved by FDA

BIOMOX® (amoxicillin)

Veterinary For Oral Suspension
For use in DOGS only.

DESCRIPTION: BIOMOX® (amoxicillin) is a broad-spectrum, semi-synthetic antibiotic which provides bacterial 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 it 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>
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

92530

05/08

Rev.-02