

FOR ANIMAL TREATMENT ONLY
RESTRICTED VETERINARY MEDICINE

Betamox LA

Highly Important Antibiotic

PRESENTATION:

Betamox LA is an off-white oily suspension for parenteral administration containing **AMOXICILLIN TRIHYDRATE BP 150 mg/mL**, with butylhydroxyanisole and butylhydroxytoluene (antioxidants).

Vial sizes: Betamox LA is presented either in clear amber glass vials (50 mL, 100 mL, 500 mL sizes) or clear PET vials (100 mL, 250 mL, 500 mL sizes).

READ THE ENTIRE LABEL BEFORE USE

INDICATIONS

Betamox LA is specifically formulated to provide antibacterial activity sustained for 48 hours following a single administration. Betamox LA is indicated for use in horses, cattle, sheep, pigs, dogs and cats, for the treatment of infections caused by, or associated with, organisms sensitive to Amoxicillin including Gram-positive bacteria – *Actinomyces*, *Bacillus*, *Staphylococcus*, *Streptococcus*, *Clostridium*, and *Erysipelothrix* spp; as well as Gram-negative bacteria – *Pasteurella*, *Bordetella*, *Brucella*, *Escherichia coli*, *Fusiformis*, *Haemophilus*, *Moraxella*, *Proteus mirabilis*, amoxicillin-sensitive *Salmonella*, *Sphaerophorus* and *Treponema* spp.

Betamox LA may be used in the treatment and control of a wide range of common systemic, respiratory and local infections caused by Amoxicillin-susceptible organisms including: Erysipelas; navel/joint ill; respiratory tract infections including pneumonia; enteritis; meningitis; septicæmia; foot abscess; urogenital tract infections and the control of secondary bacterial invaders in diseases primarily of viral origin.

Species	Disease Indications	Organisms
Cattle	Respiratory tract infections Navel/joint ill, septicæmia Enteritis infections Urogenital tract infections Intramammary infections Soft tissue infections Contagious foot rot infections	<i>Pasteurella multocida</i> and <i>Mannheimia haemolytica</i> <i>Escherichia coli</i> and <i>Streptococcal</i> spp. <i>Escherichia coli</i> <i>Corynebacterium renale</i> , <i>Streptococcus</i> spp., and <i>Proteus</i> spp. <i>Arcanobacterium pyogenes</i> , <i>Streptococcus</i> spp., <i>Staphylococcus</i> spp. (non- β lactamase producing) and <i>E. coli</i> <i>Arcanobacterium pyogenes</i> , <i>Fusobacterium necrophorum</i> and <i>Staphylococcus</i> spp. and <i>Streptococcus</i> spp. <i>Treponema</i> spp., <i>Fusobacterium necrophorum</i> and non- β lactamase producing <i>Dichelobacter nodosus</i>
Pigs	Respiratory tract infections Septicæmia & infectious arthritis Urogenital tract infections MMA syndrome Soft tissue infections	<i>Pasteurella multocida</i> and <i>Actinobacillus pleuropneumoniae</i> <i>Haemophilus parasuis</i> , <i>Actinobacillus suis</i> , <i>Streptococcus</i> spp., and <i>Erysipelas rhusiopathiae</i> <i>Actinobaculum (Eubacterium) suis</i> and <i>E.coli</i> <i>E.coli</i> and <i>Streptococcus</i> spp. <i>Staphylococcus</i> spp. and <i>Streptococcus</i> spp.
Sheep	Respiratory tract infections Omphalophlebitis, septicæmia and infectious arthritis Gastrointestinal infections Foot rot infections	<i>Pasteurella multocida</i> , <i>Bibersteinia (Pasteurella) trehalosi</i> and <i>Mannheimia haemolytica</i> <i>Erysipelas rhusiopathiae</i> , <i>Streptococcus dysgalactiae</i> , <i>Streptococcal</i> spp., <i>Fusobacterium necrophorum</i> , <i>Corynebacterium ovis</i> , and <i>E. coli</i> <i>E. coli</i> <i>Treponema</i> spp., <i>Fusobacterium necrophorum</i> and non- β lactamase producing <i>Dichelobacter nodosus</i>
Horses	Severe Respiratory infections only	<i>Bordatella</i> , <i>E. coli</i> , and <i>Streptococcus</i> spp.

Caution: Amoxicillin is contraindicated in horses except for severe respiratory infections to prevent significant adverse impacts on the bacterial flora of the caecum.

DOSAGE & ADMINISTRATION:

Betamox LA may be administered by either the intramuscular or subcutaneous route. The recommended dose rate is 15 mg Amoxicillin per kg bodyweight, which is provided by 1 mL per 10 kg bodyweight. If signs persist at 48 hours, repeat the dose. If dose volume exceeds 20 mL, it should be divided and injected at 2 separate sites.

PRUDENT USE STATEMENT:

Amoxicillin is an antibiotic in the penicillin family and is considered Highly Important to human and animal health. The use of this antibiotic should only be for the minimum period needed to meet the clinical objective. Clinical response to this antibiotic should be monitored during treatment, and choice of therapy reviewed if clinical signs of disease persist, increase, or relapse. In the event of treatment failure, culture and sensitivity should be considered to determine an appropriate alternative therapy. Indiscriminate use of this antibiotic can contribute to the development of antibiotic resistance.

CONTRA-INDICATIONS, WARNINGS, ETC:

Contra-indicated in known cases of hypersensitivity to penicillins. Do not inject intravenously.

SIDE EFFECTS:

A mild swelling or hardness may appear at the injection site, especially in horses. These reactions will resolve in 7 days.

WITHHOLDING PERIODS:

It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds.

MILK:

Cattle: Milk intended for sale for human consumption must be discarded during treatment for not less than **6 milkings** or approximately **72 hours** following the last treatment.

Sheep: Milk intended for sale for human consumption must be discarded during treatment for not less than **35 days** following the last treatment.

MEAT:

Cattle, Sheep and Pigs producing meat or offal for human consumption must not be sold for slaughter either during treatment or within **14 days** of the last treatment.

Horses producing meat or offal for human consumption must not be sold for slaughter either during treatment or within **63 days** of the last treatment.

PHARMACEUTICAL PRECAUTIONS:

Shake the vial before use.

This product does not contain an antimicrobial preservative. Use a dry, sterile needle and syringe. Swab the vial seal before removing each dose. Following withdrawal of the first dose, the vial contents should be used within 28 days. Safely discard unused material. Store below 25°C. Protect from light.

Registered pursuant to the ACVM Act 1997 No. A7950

See www.foodsafety.govt.nz for registration conditions.

Registered to & distributed by:

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Manufactured by:

Norbrook Laboratories Ltd.

Station Works, NEWRY,

Co. Down, Northern Ireland.

WARNING

Dangerous to the Environment



Handling Precautions:

Repeated exposure to Amoxicillin trihydrate may cause skin allergy. Allergic reactions to these substances may occasionally be serious. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. If you develop symptoms following exposure such as skin rash you should seek medical advice and show the doctor this package or insert. Swelling of the face, eyes or lips or difficulty with breathing are more serious symptoms and require urgent medical attention. Avoid skin contact. KEEP OUT OF REACH OF CHILDREN.

Environmental Protection: Very toxic to aquatic organisms.

Avoid contamination of any water supply with product or empty container.

Emergency Response: In case of spillage wear appropriate protective clothing and prevent material from entering waterways. Absorb spills with inert material and place in waste containers. Wash area with water and absorb with further inert material.

Disposal: Preferably dispose of product by use. Otherwise dispose of product, packaging and waste at an approved landfill or equivalent facility.

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