BINOXYL LA Suspension for Injection Amoxicillin 150mg/ml

DATA SHEET



INDICATIONS

Cattle

Bimoxyl LA Suspension for Injection is licensed for the control and treatment of respiratory and other infections caused by amoxicillin susceptible Gram-positive and Gram-negative bacteria only.

Sheep, pigs and dogs

Bimoxyl LA is licensed for the treatment of infectious diseases in pigs, sheep and dogs, caused by or associated with organisms sensitive to amoxycillin.



See reverse for Administration & Dosage

BENEFITS

- Rapid absorption
- Starts to work straight away with prolonged activity for 48 hours
- Well tolerated in cattle, sheep, pigs and dogs.
- Broad spectrum antibiotic offering cover against Gram-negative and Gram-positive organisms
- Effective against diseases of the respiratory, alimentary and urogenital tracts
- Widespread tissue distribution
- Excellent syringeability via 21 gauge needle
- Single shot treatment in most cases





Bimoxyl LA Suspension for Injection



150mg Amoxicillin/ml

PRESENTATION

A Sterile, off-white, oily, injectable suspension. Each ml contains 150mg Amoxicillin (as amoxicillin trihydrate).

TARGET SPECIES

Cattle, sheep, pigs and dogs.

INDICATIONS FOR USE

Cattle: Bimoxyl LA is licensed for the control and treatment of respiratory and other infections caused by amoxicillin susceptible Gram-positive and Gram-negative bacteria only.

Sheep, pigs and dogs: Bimoxyl LA is licensed for the treatment of infectious diseases in pigs, sheep and dogs, caused by or associated with organisms sensitive to amoxycillin.

CONTRAINDICATIONS

Not suitable for intravenous or intrathecal administration.

Not to be administered to small herbivores. Do not use in known cases of hypersensitivity to beta-lactam antibiotics.

SPECIAL WARNINGS FOR EACH TARGET SPECIES

Not effective against Beta-lactamase producing organisms.

SPECIAL PRECAUTIONS FOR USE

(i) Precautions for use in animals

Routine aseptic precautions should be taken. (ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. 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.

Handle this preparation with great care to avoid exposure, taking all recommended precautions. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the Doctor this warning.

Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

ADVERSE REACTIONS (FREOUENCY AND **SERIOUSNESS)**

As with all penicillins, amoxicillin may cause hypersensitivity (allergy) and should not be used when an animal is known to be allergic to beta-lactams.



Occasional local reaction of a transient nature may occur at the site of injection.

USE DURING PREGNANCY. LACTATION OR LAY

As with all other antibiotics, Bimoxyl LA should be used with caution during pregnancy and lactation. There is no evidence that the use of amoxicillin presents any particular hazard either to the dam or to the foetus.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF **INTERACTION**

Bimoxyl LA is unlikely to interact significantly with any other drugs commonly administered to animals.

It is not recommended to administer bactericidal and bacteriostatic antibiotics concomitantly.

AMOUNTS TO BE ADMINISTERED AND **ADMINISTRATION ROUTE**

This product does not contain an antimicrobial preservative. Use a dry, sterile needle and syringe. Swab the septum before removing each dose. Shake the vial well before use.

Cattle, Sheep & Pigs: By intramuscular route only.

Dogs: By subcutaneous injection.

The injection site should be massaged after iniection.

The recommended dosage rate is 15 mg amoxicillin per kg bodyweight. This is equivalent to 1 ml/10 kg.

One repeat administration may be given after 48 hours.

The maximum injection volume at any one site is: Cattle: 20 ml:

Sheep: 4 ml; Pigs: 5 ml; Dogs: 2.5 ml.

Larger dose volumes should be divided and given into separate sites.

Ŭse a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

OVERDOSE (SYMPTOMS, **EMERGENCY PROCEDURES, ANTIDOTES), IF NECESSARY**

The safety of amoxicillin is typical of that of other penicillins in that intrinsic toxicity is very low, except in animals with specific allergy to the Beta-lactams, and this seems rare. Tolerance studies at twice the normal recommended dose in the named target species have been carried out

WITHDRAWAL PERIOD(S)

i) Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 21 days from the last treatment.

Sheep may be slaughtered for human consumption only after 25 days from the last treatment.

be slaughtered for human Pigs may consumption only after 13 days from the last treatment.

ii) Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken only from cattle after 156 hours from the last treatment.

iii) Not for use in ewes producing milk for human consumption or food processing.

MAJOR INCOMPATIBILITIES

Exposure to moisture will lead to hydrolysis of the active substance.

SHELF LIFE

2 Years.

Following withdrawal of the first dose, use the product within 28 days.

SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C. Protect from light.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM THE **USE OF SUCH PRODUCTS IF APPROPRIATE**

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

LEGAL CATEGORY POM

PACKAGE QUANTITIES

Multidose vials of 100ml

MARKETING AUTHORISATION NUMBER VPA 22033/039/001

MARKETING AUTHORISATION HOLDER

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A full product SPC is available on request from Bimeda or alternatively can be found on the HPRA website.

