

BIMOXYL L.A. INJECTION

150mg Amoxicillin/ml

INDICATIONS

Contains amoxicillin which is a member of the penicillin family.

Cattle and Sheep: For the control and treatment of respiratory and other infections caused by amoxycillin susceptible bacteria only.

Pigs: For the treatment of infectious diseases in pigs caused by or associated with organisms sensitive to amoxycillin.

Dogs: For the treatment of infectious diseases in dogs caused by or associated with organisms sensitive to amoxycillin

BENEFITS

- Rapid absorption due to the patented penetration enhancer incorporated into the formulation
- 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



PACKAGING

LIST NO.	UNIT PACKAGE	CASE SIZE
1BIM028	100 ml	12

See reverse side for Administration and Dosage.



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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 and Sheep: For the control and treatment of respiratory and other infections caused by amoxicillin susceptible bacteria only.

Pigs: For the treatment of infectious diseases in pigs caused by or associated with organisms sensitive to amoxicillin.

Dogs: For the treatment of infectious diseases in dogs caused by or associated with organisms sensitive to amoxicillin.

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 (FREQUENCY 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 injection.

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.

Use 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.

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

ii) Milk for human consumption must not be taken during treatment. Milk from 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.

MARKETING AUTHORISATION HOLDER

Bimeda Chemicals Ltd., Broomhill Road, Tallaght, Dublin 24. Ireland.

MARKETING AUTHORISATION NUMBER

VPA10126/009/001

LEGAL CATEGORY

POM-V

PACKAGE QUANTITIES

Multidose vials of 100ml

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

