

Bimeda

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Bimoxyl LA 150 mg/ml Amoxicillin Suspension for Injection

Species:	Cattle, Dogs, Pigs, Sheep
Therapeutic indication:	Pharmaceuticals: Antimicrobials: Injections
Active ingredient:	Amoxicillin Trihydrate
Product:	Bimoxyl LA 150 mg/ml Amoxicillin Suspension for Injection
Product index:	Bimoxyl LA 150 mg/ml Amoxicillin Suspension for Injection
Cattle - milk:	72 hours
Cattle - meat:	21 days
Sheep - meat:	19 days
Pig - meat:	24 days
Withdrawal notes:	Not for use in ewes producing milk for human consumption or food processing
Incorporating:	

Qualitative and quantitative composition

Active substances:

Each ml contains 150 mg Amoxicillin
(as Amoxicillin Trihydrate)

Pharmaceutical form

A cream to off white suspension for injection. Any settlement should reconstitute on normal shaking.

Clinical particulars

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.

Contra-indications

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

Precautions for use in animals

Routine aseptic precautions should be taken.

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

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.

Interactions

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

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 with no adverse effects being observed. Treatment is symptomatic.

Withdrawal periods

Cattle: Meat and offal: 21 days

Milk: 72 hours

Sheep: Meat and offal: 19 days

Not authorised for use in sheep producing milk for human consumption.

Pigs: Meat and offal: 24 days.

Pharmaceutical particulars

List of Excipients

Propylene glycol dicaprylocaprate,
Aluminium stearate,
Glycerol monocaprylate (type 1).

Major incompatibilities

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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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.

Immediate packaging

100 ml glass (Type II) multidose type siliconised vials closed with a rubber bung and containing an oily suspension of amoxicillin trihydrate.

Disposal

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

Marketing Authorisation Number

Vm 50146/4010

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 13/12/1990

Date of revision of the text

October 2018

Any other information

Nil

Legal category

Legal category: POM-V

GTIN

GTIN description: Bimoxyl LA 100mls

GTIN: 5391510230359

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