

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimoxyl LA 150 mg/ml suspension for injection for cattle, sheep, pigs and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Amoxicillin 150 mg
(as Amoxicillin Trihydrate)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Propylene glycol dicaprylocaprate	
Aluminium stearate	
Glycerol monocaprylate (type I)	

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, pigs and dogs.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Not suitable for intravenous or intrathecal administration.

Not to be administered to small herbivores.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Not effective against Beta-lactamase producing organisms.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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. People with known hypersensitivity to amoxicillin should avoid contact with the veterinary medicinal product.

Handle this preparation with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep, pigs and dogs:

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity ¹ Injection site reaction ²
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¹As with all penicillins and should not be used when an animal is known to be allergic to beta-lactams.

²Transient nature.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

As with all other antibiotics, the veterinary medicinal product 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.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product is unlikely to interact significantly with any other drugs commonly administered to animals.

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

3.9 Administration routes and dosage

Cattle, sheep & pigs: Intramuscular use.

Dogs: Subcutaneous use.

The veterinary medicinal 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.

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.

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.

One repeat administration may be given after 48 hours. For intramuscular injections, separate site(s) to the first injection(s) must be used.

Use a dry sterile needle and 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.

The closure should not be pierced more than 30 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01 CA04

4.2 Pharmacodynamics

The veterinary medicinal product contains 150mg Amoxicillin per ml and is intended for parenteral administration.

Amoxicillin is a broad spectrum antibiotic of the penicillin group which in turn is a member of the beta-lactam group.

The mode of action of beta-lactams which involves interference with cell wall synthesis is most effective when bacteria are actively multiplying and the cell wall is growing. At high dose levels the penicillins have additional bactericidal effects within the bacterial cell and may affect dormant bacteria.

4.3 Pharmacokinetics

Beta-lactam antibacterials are generally excreted rapidly and unchanged in the urine. The use

of a suspension product prolongs effective concentrations in the blood and fluids.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 Years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

100 ml Type II siliconised glass or clear type I glass multidose vials sealed with rubber stoppers and aluminium overseals.
100 ml Polyethylene terephthalate (PET) vials sealed with a chlorobutyl stopper and an aluminium cap with plastic flipoff seal packed individually into outer cartons.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER

Vm 50146/4010

8. DATE OF FIRST AUTHORISATION

13 December 1990

9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

March 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 17 March 2026