1. NAME OF 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
Aluminium stearate
Glycerol monocaprylate
Propylene glycol dicaprylocaprate

A cream to off-white oily suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, pigs and dogs.

3.2 Indications for use for each target species

Cattle: For the treatment of respiratory and other infections caused by amoxicillin susceptible Gram-positive and Gram-negative bacteria only.

Sheep, pigs and dogs: For the treatment of infectious diseases in pigs, sheep and 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.
Not for use in ewes producing milk for human consumption or food processing.
Do not use in cases of hypersensitivity to penicillin or to the active substance.

3.4 Special warnings for each target species

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 active substance should avoid contact with the veterinary medicinal product.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the package leaflet or label to the physician. Swelling of the face, lips and 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]

1. The product should not be used when an animal is known to be allergic to penicillins.
2. Transient 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 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

None known.

3.9 Amounts to be administered and administration route

Cattle, sheep & pigs: Intramuscular use
Dogs: Subcutaneous 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. Swab the septum before removing each dose.

Shake well before use.

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.

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: 18 days.
Milk: 72 hours.

Sheep: Meat and offal: 21 days.
Not authorised for use in sheep producing milk for human consumption.

Pigs: Meat and offal: 21 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CA04

4.2 Pharmacodynamics

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 involves interference with cell wall synthesis. These drugs are therefore more effective when 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

Amoxicillin is mainly distributed to the extra-cellular compartment. Its distribution into tissues is facilitated by its low degree of plasma protein binding (17%). Concentrations in pulmonary, pleural and bronchial tissues are similar to plasma concentrations. Amoxicillin diffuses into

pleural and synovial fluid and into lymphatic tissue. Amoxicillin is biotransformed in the liver by hydrolysis of the ß-lactam ring leading to inactive penicilloic acid (20%). Amoxicillin is mainly excreted in active form via the kidneys, and secondarily by the biliary route and through milk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.
Store in a dry place.

5.4 Nature and composition of immediate packaging

100 ml clear glass (Type I or II) multidose type vials sealed with a bromobutyl rubber stopper and capped with aluminium overseal.
100 ml and 250 ml polyethylene terephthalate (PET) vials with a chlorobutyl stopper and an aluminium cap with plastic flipoff seal.

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(S)

VPA22033/039/001

8. DATE OF FIRST AUTHORISATION

01/10/1987

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

07/02/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).