SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimoxyl LA, 150 mg/ml amoxicillin, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active substances

Each ml contains 150 mg Amoxicillin
(as Amoxicillin Trihydrate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, pigs and dogs.

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

Not effective against Beta-lactamase producing organisms.

4.5 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.

4.6 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.

4.7 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.

4.8 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.

4.9 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. 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 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.

4.10 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 with no adverse effects being observed. Treatment is symptomatic.

4.11 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.

5. PHARMACEUTICAL PROPERTIES

The 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.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 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.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days

6.5 Nature and composition of immediate packaging

100 ml Type II siliconised glass or clear type I glass multidose vials closed with rubber bungs and aluminium overseals or 100 ml Polyethylene terephthalate (PET) vials with a chlorobutyl stopper and

an aluminium cap with plastic flipoff seal packed individually into outer cartons.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

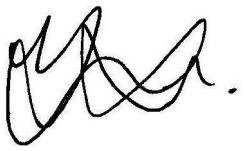
Vm 50146/4010

9. DATE OF FIRST AUTHORISATION

13 December 1990

10. DATE OF REVISION OF THE TEXT

September 2022



Approved: 14 September 2022