SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox LA 150 mg/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each ml contains:
150 mg (15% w/v) Amoxicillin
(as Amoxicillin Trihydrate 17.21 %w/v),

Excipients:
0.08 mg (0.008% w/v) butylated hydroxytoluene
0.08 mg (0.008% w/v) butylated hydroxyanisole as antioxidants.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
An off-white oily non-aqueous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, Sheep, Pigs, Dogs, Cats

4.2 Indications for use, specifying the target species

In vitro Amoxicillin is effective against a wide range of Gram-positive and Gram-negative bacteria which include:

Escherichia coli
Klebsiella pneumoniae
Proteus species
Salmonella species
Staphylococci and
Streptococci

Not effective against beta-lactamase producing organisms.

Suitable for the control of infections due to susceptible microorganisms in cattle, sheep, pigs, dogs and cats where a single injection giving prolonged activity is required. It may also protect from secondary bacterial invasion due to sensitive organisms in cases where bacteria are not the initial cause of the disease.

Indications include infections of:

(a) Alimentary tract
(b) Respiratory tract
(c) Skin and soft tissue
(d) Urogenital tract and,
(e) In prevention of post-operative infection (treat before surgery).

4.3 Contraindications

This product is not suitable for intravenous or intrathecal use

This product should not be administered to rabbits, hamsters, gerbils or guinea pigs.

Not for use in known cases of hypersensitivity to penicillins or cephalosporins.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

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

3. If you develop symptoms following exposure such as 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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, hypersensitivity reactions such as urticaria anaphylaxis shock can

occur after use. In the case of allergic reactions, treatment should be discontinued and a symptomatic treatment should be initiated. In very rare cases, local tissue reactions such as swelling and pruritus may result from the use of amoxicillin.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

It is not generally recommended to use bactericidal and bacteriostatic antibiotics at the same time.

4.9 Amounts to be administered and administration route

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing or overdosing.

Cattle, sheep and pigs - By intramuscular injection only.

Dogs and cats - By subcutaneous or intramuscular injection.

The recommended dosage rate is 15 mg per kg bodyweight, repeatable if necessary after 48 hours. Massage the injection site.
Shake the vial before use
Swab the septum before removing each dose. Use a dry sterile needle and syringe.
A separate injection site should be used for each administration.

Animal	Weight (kg)	Dosage volume (ml)
Cattle	450 kg	45.0 ml
Sheep	65 kg	6.5 ml
Pigs	150 kg	15.0 ml
Dogs	20 kg	2.0 ml
Cats	5 kg	0.5 ml

Dose volume is equivalent to 1 ml per 10 kg bodyweight. If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided and injected into two or more sites. As with other injectable preparations, normal aseptic precautions should be observed as this product does not contain antimicrobial preservative.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

If no distinct clinical response is seen after the second treatment, a check of the diagnosis and eventually a change of treatment are required.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Penicillins have a wide safety margin.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 39 days
Milk: 108 hours (4.5 days)

Pigs:
Meat and offal: 42 days

Sheep:
Meat and offal: 29 days
Milk: Not authorised for use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial
ATC Vet Code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxicillin has a unique mode of action which directly and irreversibly disrupts existing cell wall peptidoglycan rather than newly forming peptidoglycan of the divisory septal wall as with other members of the penicillin family.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Aluminium Stearate
Propylene Glycol Dicaprylocaprate

6.2 Major incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
This product does not contain an antimicrobial preservative.

6.5 Nature and composition of immediate packaging

100 ml and 50 ml clear, colourless Type II or III multidose glass vials, closed with nitrile rubber bungs and aluminium overseals.
50 ml, 100 ml, 250 ml and 500 ml clear polyethylene terephthalate vials sealed with nitryl bungs and aluminium overseals.

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

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4070

9. DATE OF FIRST AUTHORISATION

30 June 1986

10. DATE OF REVISION OF THE TEXT

July 2025

Gavin Hall
Approved: 28 July 2025