1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox LA 150 mg/ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each ml contains 150 mg amoxicillin equivalent to 172.1 mg 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**
butylated hydroxytoluene (E321	0.08 mg/ml
butylated hydroxyanisole (E320)	0.08 mg/ml
Aluminium Distearate	
Propylene Glycol Dicaprylocaprate	

An off-white suspension.

3. CLINICAL PARTICULARS

3.1 Target Species

Cattle, sheep, pigs, dogs, cats.

3.2 Indications for use, specifying the target species.

For the treatment of infections caused by a wide range of Gram-positive and Gram-negative pathogenic bacteria including:

Bacillus anthracis
Bacillus cereus
Bordetella bronchiseptica
Clostridium spp.
Corynebacterium spp.
Erysipelothrix rhusiopathiae
Escherichia coli
Haemophilus spp.
Pasteurella spp.
Proteus mirabilis
Salmonella spp.
non-penicillinase producing staphylococci
non-penicillinase producing streptococci
Fusiformis spp.

The veterinary medicinal product is suitable for the control of infections due to susceptible micro-organisms in cattle, sheep, pigs, dogs and cats where a single injection giving prolonged activity is required. It may also protect from secondary bacterial invasion in cases where bacteria are not the initial cause of 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).

3.3 Contraindications

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

Not for intravenous or intrathecal use.
Do not use in rabbits, hamsters, gerbils and guinea pigs.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals.

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances are occasionally serious.

1. People with known hypersensitivity to penicillin or cephalosporins should avoid contact with the veterinary medicinal product.

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

3. If you develop symptoms following exposure, such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment
Not applicable.

3.6 Adverse events

Target species: Cattle, sheep, pigs, dogs, cats.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction Hypersensitivity reaction

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:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interactions

None known.

3.9 Administration routes and dosage

Cattle, sheep and pigs – By intramuscular injection only.
Dogs and cats – By subcutaneous or intramuscular injection.
Shake bottle well before use.
Use a dry syringe for extraction of the suspension.

The dosage rate is 15 mg/kg bodyweight repeatable if necessary, after 48 hours.
Massage the injection site.

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

Dose volume is equivalent to 1 ml per 10 kg body weight. 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.
Normal aseptic precautions should be observed.

The stopper should not be punctured more than 33 times.

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

Not applicable.

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: 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.

4. PHARMACOLOGICAL or IMMUNOLOGICAL INFORMATION

4.1 ATCvet Code:
QJ01CA04.

4.2 Pharmacodynamics

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.

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: 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

The veterinary medicinal product is supplied in one 50 ml or 100 ml Type II glass vial in a cardboard box, sealed with nitryl rubber bung and aluminium overseal and one 50 ml, 100 ml or 250 ml clear polyethylene terephthalate (PET) vial in a cardboard box, sealed with nitryl rubber bung and aluminium overseal.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

6. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/010/001

8. DATE OF FIRST AUTHORISATION

01 October 1987

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

12 June 2024

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).