1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox 150 mg/ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance: amoxicillin (as Amoxicillin Trihydrate) 150 mg
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 INFORMATION

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

3.3 Contraindications

Not for intravenous or intrathecal use.
Do not use in rabbits, hamsters, gerbils and guinea pigs.
Do not use in sheep producing milk for human consumption.

3.4 Special warnings

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:

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 can occasionally be serious.

People with known hypersensitivity to Amoxicillin Trihydrate should avoid contact with the veterinary medicinal product. Administer the veterinary medicinal product with caution.

Handle this product 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

In case of accidental self-administration/ self-injection ingestion/ spillage onto skin, 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.

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic-type reaction[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction

[1]May occur following use of amoxicillin containing products.

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 interaction

None known.

3.9 Administration routes and dosage

Administration is by the intramuscular or subcutaneous route.

Shake bottle before use.

Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin.

The dosage rate is 7 mg/kg daily for up to 5 days in all species.

Massage the injection site.

Animal	Weight (kg)	Dose volume (ml)
Cattle	450	20.00
Sheep	65	3.00
Pigs	150	7.00
Dogs	20	1.00
Cats	5	0.25

(Guide-dose volume is approximately equivalent to 0.25 ml per 5 kg daily).

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: 18 days.
Milk: 48 hours.

Sheep:
Meat and offal: 7 days.

Pigs:
Meat and offal: 14 days.

4. PHARMACOLOGICAL 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 product is supplied in one 50 ml or 100 ml Type II glass vial in a cardboard box, sealed with a nitryl bung and aluminium seal and one 50 ml or 100 ml plastic (PET) vial in a cardboard box, sealed with a nitryl bung and aluminium seal.

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 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. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/004/001

8. DATE OF FIRST AUTHORISATION

01/10/1987

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

05/04/2024

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).