Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox LA 150 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance		
Amoxicillin as Amoxicillin Trihydrate	150	mg
Excipients		
Butylated hydroxyanisole E320	0.08	mg
Butylated hydroxytoluene E321	0.08	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.
An off-white oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle
Sheep
Pigs
Dogs
Cats

4.2 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 staphylococci
Erysipelothrix rhusiopathiae	non-penicillinase producing streptococci
Escherichia coli	*Fusiformis* spp.

Betamox LA 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).

4.3 Contraindications

Not for intravenous or intrathecal use.

Do not use in rabbits, hamsters, gerbils and guinea pigs.

Do not use in known cases of hypersensitivity to amoxycillin.

4.4 Special warnings for each target species

None known.

4.5 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. 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 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.

4.6 Adverse reactions (frequency and seriousness)

Occasional local tissue reaction may result from use of this product.
Occasional hypersensitivity-type reactions may occur following use of this product.

4.7 Use during pregnancy, lactation or lay

Betamox LA can be safely administered during pregnancy and lactation. When used in lactating cows, the necessary withdrawal period should be observed.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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 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.

Normal aseptic precautions should be observed.

The stopper should not be punctured more than 33 times.

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

Not applicable.

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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterial.
ATCvet Code: QJ01CA01.

5.1 Pharmacodynamic properties

Amoxycillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxycillin 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 hydroxytoluene
Butylated hydroxyanisole
Aluminium stearate
Propylene glycol dicaprylocaprate

6.2 Major incompatibilities

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 after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1987
Date of last renewal: 06 February 2009

10 DATE OF REVISION OF THE TEXT

January 2021