Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox 150 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
150 mg amoxicillin (as Amoxicillin Trihydrate), and 0.08 mg butylated hydroxytoluene (E321) and 0.08 mg butylated hydroxyanisole (E320) as antioxidants.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.
An off-white 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
Bacillus cereus
Bordetella bronchiseptica
Clostridium spp.
Corynebacterium spp.
Erysipelothrix rhusiopathiae
Escherichia coli
Fusiformis spp.
Haemophilus spp.
Pasteurella spp.
Proteus mirabilis
Salmonella spp.

Non-penicillinase producing Staphylococci
Non-penicillinase producing Streptococci

4.3 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.
Do not use in known cases of hypersensitivity to amoxicillin/penicillin.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special Precautions to be taken by the Person Administering the 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.

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.
On rare occasions anaphylactic reactions may occur following use of amoxicillin containing products.

4.7 Use during pregnancy, lactation or lay

Betamox can be safely administered to pregnant and lactating animals

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

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.

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

Not applicable

4.11 Withdrawal period(s)

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 48 hours from the last treatment. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 7 days from the last treatment. Pigs may be slaughtered for human consumption only after 14 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Beta-lactam antibacterials
ATCvet 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 hydroxytoluene (E321)
Butylated hydroxyanisole (E320)
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 product is supplied in 50 ml and 100 ml Type II glass vials sealed with a nitryl bung and aluminium seal and 50 ml and 100 ml plastic (PET) vials sealed with a nitryl bung and aluminium seal.

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)

VPA22664/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 January 1987
Date of last renewal: 13 March 2009

10 DATE OF REVISION OF THE TEXT

January 2019