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

Active Substance:

Amoxicillin	150 mg
(as Amoxicillin Trihydrate	172.1 mg)

Excipients:

Butylated Hydroxyanisole	0.08 mg
Butylated Hydroxytoluene	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:

Actinobacillus equuli
Actinobacillus lignieresi
Erysipelothrix rhusiopathiae
Escherichia coli
Haemophilus species
Pasteurella species
Proteus mirabilis
Actinomyces bovis
Bacillus anthracis
Bordetella bronchiseptica
Clostridium species
Corynebacterium species
Fusiformis species
Moraxella species

Salmonella species
Staphylococci
Streptococci
Not effective against beta-lactamase producing organisms.

4.3 Contraindications

Intravenous or intrathecal use.
Use in rabbits, hamsters, gerbils and guinea pigs.
Use in known cases of hypersensitivity to amoxycillin.

4.4 Special Warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

None

ii. 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.

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

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 or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Occasional local tissue reactions may result from use of this product.

4.7 Use during pregnancy, lactation or lay

Betamox Iniection can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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.

The recommended dosage rate is 7 mg/kg bodyweight once a day for up to five days. Massage the injection site.

A separate injection site should be used for each administration.

Animal	Weight (kg)	Dose volume (ml)
Cattle	450	20.0
Sheep	65	3.0
Pigs	150	7.0
Dogs	20	1.0
Cats	5	0.25

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

Normal aseptic precautions should be observed. Shake vial before use. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

If dose volume exceeds 20 ml in cattle or 10 ml in pigs, it should be divided and injected into two sites.

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

Penicillin's have a wide safety margin

4.11 Withdrawal period

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 24 hours from the last treatment.

Not for use in sheep producing milk for human consumption.

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 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 16 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ 01 CA 04

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 Hydroxyanisole
Butylated Hydroxytoluene
Aluminium Stearate
Propylene Glycol Dicaprylocaprate

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

Betamox Injection is supplied in 50 ml and 100 ml clear, colourless Type III or Type II glass vials, closed with nitrile rubber bungs and aluminium overseals, and 50 ml and 100 ml clear plastic vials closed with nitrile rubber bungs and aluminium overseals.
Not all pack sizes may be marketed.

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

Any unused veterianry medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4071

9. DATE OF FIRST AUTHORISATION

30 June 1986

10. DATE OF REVISION OF THE TEXT

January 2020

Approved 27 January 2021