SUMMARY OF PRODUCT CHARCTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare Suspension for Injection 15% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active Substance(s)	**mg**
Amoxicillin	150.0
(as Amoxicillin Trihydrate	172.1

Excipients

Butylated Hydroxytoluene	0.08 (as antioxidant)
Butylated Hydroxyanisole	0.08 (as antioxidant)

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:

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

Proteus mirabilis
Salmonella species
Staphylococci
Streptococci
Moraxella species

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 Amoxicillin.

4.4 Special Warnings for each target species

None known.

4.5 Special precautions for use

i Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

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.

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 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 reaction may result from use of this product.

4.7 Use during pregnancy, lactation or lay

Can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

It is not generally recommended to use bactericidal and bacteriostatic antibiotics at the same time.

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.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
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).

Maximum dose volumes at one injection site are 20 ml cattle, 10 ml sheep and pigs. An appropriate graduated syringe must be used when administering small volumes to ensure accurate dosing. 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.

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

Penicillins have a remarkably good safety record and overdose is highly unlikely.

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: 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. Amoxicillin is well absorbed after parenteral administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Aluminium Stearate
Propylene Glycol Dicaprylocaprate

6.2 Incompatibilities

None.

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

Amoxycare Suspension for Injection 15% w/v is supplied in:
- 50 ml and 100 ml clear glass type II vials closed with nitrile rubber bungs and aluminium overseals.
- 50 ml and 100 ml clear polyethylene terephthalate (PET) 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 veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with 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 02000/4140

9. DATE OF FIRST AUTHORISATION

9 January 1998

10. DATE OF REVISION OF THE TEXT

January 2021

Approved 27 January 2021