SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare LA 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

In vitro amoxicillin is effective against a wide range of Gram-positive and Gram-negative bacteria which include:

Escherichia coli
Klebsiella pneumoniae
Proteus species
Salmonella species
Staphylococci and
Streptococci
Not effective against beta-lactamase producing organisms.

Amoxycare LA Injection 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 due to sensitive organisms in cases where bacteria are not the initial cause of the 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

This product is not suitable for intravenous or intrathecal use.

This product should not be administered to rabbits, hamsters, gerbils or guinea pigs.

Not for use in known cases of hypersensitivity to penicillins or cephalosporins.

4.4 Special Warnings for each target species

No special warnings.

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.
Shake well before use. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. This product does not contain an antimicrobial preservative.

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 skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, hypersensitivity reactions such as urticaria anaphylaxis shock can occur after use. In the case of allergic reactions, treatment should be discontinued and a symptomatic treatment should be initiated. In very rare cases, local tissue reactions such as swelling and pruritus may result from the use of amoxicillin.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Amoxycare LA Injection can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

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 15 mg per kg bodyweight, repeatable if necessary after 48 hours. Massage the injection site.

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

Swab the septum before removing each dose. Use a dry sterile needle and syringe. A separate injection site should be used for each administration.

Animal	Weight (kg)	Dosage volume (ml)
Cattle	450 kg	45.0 ml
Sheep	65 kg	6.5 ml
Pigs	150 kg	15.0 ml
Dogs	20 kg	2.0 ml
Cats	5 kg	0.5 ml

Dose volume is equivalent to 1 ml per 10 kg body weight. 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. As with other injectable preparations normal aseptic precautions should be observed as this product does not contain antimicrobial preservative.

An appropriate graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

If no distinct clinical response is seen after the second treatment, a check of the diagnosis and eventually a change of treatment are required.

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

Not applicable.

4.11 Withdrawal period

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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Aluminium Stearate
Propylene Glycol Dicaprylocaprate

6.2 Major 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

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

6.5 Nature and composition of immediate packaging

Amoxycare LA Suspension for Injection 15% w/v is supplied in:
- 50 ml and 100 ml clear glass type II vials sealed with nitrile bungs and aluminium overseals.
- 50 ml, 100 ml, 250 ml and 500ml clear polyethylene terephthalate (PET) plastic vials sealed with nitrile 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
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

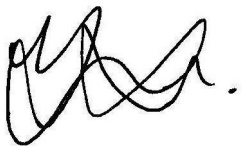
Vm 02000/4141

9. DATE OF FIRST AUTHORISATION

05 November 1997

10. DATE OF REVISION OF THE TEXT

March 2022



Approved: 01 March 2022