SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 300 Solution for Injection 300 mg/ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:	**%w/v**
Oxytetracycline	30.00
(as Oxytetracycline dihydrate	32.40)

Excipients:	
Sodium Formaldehyde Sulphoxylate Anhydrous	0.40

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
Clear dark amber liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Sheep
Pigs

4.2 Indications for use, specifying the target species

For the treatment of conditions caused by or associated with organisms sensitive to oxytetracycline including:
Bordetella bronchiseptica
Actinomyces pyogenes
Erysipelothrix rhusiopathiae
Pasteurella spp
Staphylococcus spp
Streptococcus spp

Certain mycoplasma, rickettsiae, protozoa and chlamydia are also sensitive to oxytetracycline.

The product is indicated for the treatment and control of pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, joint-ill, navel-ill, summer mastitis in cows, ovine keratoconjunctivitis (pink-eye) and enzootic abortion in sheep.

4.3 Contraindications

Do not dilute the product.

4.4 Special Warnings for each target species

Oxytetracycline therapy does not completely eliminate chlamydial infection in the flock.

4.5 Special precautions for use

Special precautions for use in animals

If concurrent treatment is administered, use a separate injection site. Resistance against oxytetracycline may vary.
Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Inappropriate use of the product may increase the prevalence of bacteria resistant to oxytetracycline and may decrease the effectiveness of treatment with tetracyclines due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product may cause hypersensitivity reactions (allergy). Persons with a known hypersensitivity to tetracyclines should not handle this product. Wash hands after use. In case of contact with eyes or skin, wash off immediately with water as irritation may occur. Avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

Although the product is well tolerated, occasionally a slight local reaction of a transient nature may be observed. Collapse has been reported with tetracyclines in weak or debilitated animals.
Other adverse reactions to oxytetracycline that have been observed include gastrointestinal disorders and, less frequently, allergic and photosensitivity reactions.
In very rare cases, hypersensitivity, allergic or anaphylactic type reactions may occur and in extreme cases these may be fatal. If such reactions occur, appropriate treatment is recommended

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

The use of this product during the period of tooth and bone development, including late pregnancy, may lead to discoloration. The product can be safely administered during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Oxytetracycline may interfere with the action of bactericidal antimicrobials, such as penicillins and cephalosporins, and therefore they should not be used simultaneously.
Concomitant vaccination is not recommended because of possible immuno-suppressive activity of tetracyclines.

4.9 Amounts to be administered and administration route

To ensure a correct dosage, bodyweight should be determined as accurately as possible, to avoid underdosing.
Deep intramuscular injection.

Alamycin LA 300 can be administered at the standard dose of 20 mg/kg to obtain 3 to 4 days duration of activity or at a high dose of 30 mg/kg for prolonged duration of activity (i.e. activity maintained for 5 to 6 days).

Cattle, Sheep and Pigs: Standard dose - 20 mg/kg (1ml/15kg)
High dose - 30 mg/kg (1ml/10kg)

Maximum recommended dosage at one site:

Cattle	15 ml
Pigs	10 ml
Sheep	5 ml
Piglets	1 day: 0.2ml
	7 days: 0.3 ml
	14 days: 0.4 ml
	21 days: 0.5 ml
	Over 21 days: 1ml/10 kg

This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a sterile needle and syringe.

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

Excessive dosages can cause nephrotoxicity in cattle. No treatment specified.

4.11 Withdrawal period

20 mg/kg dose:

Cattle – Meat & offal	28 days	Pigs – Meat & offal	14 days
Sheep – Meat & offal	28 days		

30 mg/kg dose:

Cattle – Meat & offal	35 days
Pigs – Meat & offal	28 days
Sheep – Meat & offal	28 days

Cattle – Milk 8 days
Sheep – Milk 8 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial

ATC Vet Code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the aminoactyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

The product is specifically formulated to provide a prolonged action, resulting in sustained antibacterial activity. Following intramuscular administration, effective blood levels persist for 3-4 days at a dose rate of 20mg/kg and for 5-6 days at a dose rate of 30mg/kg. Maximum blood levels are achieved between 4-6 hours following administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate Anhydrous
Magnesium Oxide Light
Dimethylacetamide
Ethanolamine (for pH adjustment)
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after 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 safely
This product does not contain any microbial preservative.

6.5 Nature and composition of immediate packaging

100 ml, 250 ml and 500 ml amber glass Type I vial with bromobutyl rubber bung with aluminium seal.
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 product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4113

9. DATE OF FIRST AUTHORISATION

13 December 1993

10. DATE OF REVISION OF THE TEXT

March 2025

Gavin Hall

Approved 20 March 2025