SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 200 mg/ml Solution for Injection for Cattle, Sheep and Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance

Oxytetracycline 200 mg

(Equivalent to Oxytetracycline Dihydrate 216 mg)

Excipients

Sodium Formaldehyde Sulfoxylate (2 mg)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

A clear amber solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

The product is indicated for use in cattle, sheep and pigs in the treatment of:

- Atrophic rhinitis caused by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida.*
- Navel/joint ill caused by *Trueperella pyogenes, E. coli* or *Staphylococcus aureus.*
- Mastits caused by *Corynebacterium pyogenes, E. coli, Staphylococcus aureus, Streptococcus agalactiae* or *Streptococcus uberis.*

- Metritis caused by *E. coli* or *Streptococcus pyogenes*.
- Pasteurellosis and infections of the respiratory tract caused by *Mannheimia haemolytica* and *Pasteurella multocida.*
- Septicaemia caused by *Salmonella dublin* and *Streptococcus pyogenes*.
- Erysipelas caused by *Erysipelothrix rhusiopathiae.*

The product can also be used in the control of enzootic abortion in sheep.

4.3 Contraindications

Do not use in horses, dogs, cats.

Do not use in animals suffering from hepatic or renal damage.

4.4 Special Warnings for Each Target Species

None

4.5 Special Precautions for Use

i. Special Precautions for use in animals

Do not dilute the product.

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 and taking into account official and local antimicrobial policies.

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.

ii. 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 immediately with plenty of water as irritation may occur.

Take care to avoid accidental injection.

4.6 Adverse reactions (frequency and seriousness)

Local reactions at the injection site may occur.

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. 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 oxytetracycline during the period of tooth and bone development, including late pregnancy may lead to tooth discoloration, the product can be safely administered to lactating animals.

4.8 Interactions 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 Amount to be administered and administration route

The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. The product is recommended for a single administration only.

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

Maximum recommended dose at any one site:

Cattle :	20ml
Pigs :	10ml
Sheep :	5ml
Piglets:	1 day 0.2ml
	7 days 0.3ml
	14 days 0.4ml
	21 days 0.5ml
	Over 21 days 1.0 ml/10kg.

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

There is no known specific antidote, if signs of possible overdose occur, treat the animal symptomatically.

4.11 Withdrawal periods

Cattle:	Meat and offal – 41 days
	Milk – 8 days
Sheep:	Meat and offal – 24 days
	Milk – 7 days
Pigs:	Meat and offal – 20 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATCvet 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 aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of 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.

Oxytetracycline had been shown to be effective in vitro against the following bacterial species: *Bordetella bronchiseptica, Corynebacterium pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Histophilus somni, Pasteurella haemolytica, Pasteurella multocida, Salmonella dublin, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes* and *Streptococcus uberis*.

5.2 Pharmacokinetic properties

Blood levels persist for at least 4 days after administration by the intramuscular route. Maximum blood levels are achieved between 4 and 8 hours following intramuscular administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium formaldehyde sulfoxylate

Magnesium Oxide Light

2-Pyrrolidone

Povidone K12

Monoethanolamine

Hydrochloric Acid

Water for Injections

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 25ºC. Protect from light.

Following withdrawal of the first dose, use the product within 28 days.
Discard unused material

When the vial has been broached and contents exposed to air, the solution may darken but the potency will be unchanged.

6.5 Nature and composition of immediate packaging

Amber type II glass vials of 50 ml and 100 ml sealed with Chlorobutyl Rubber Bungs 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, if appropriate

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

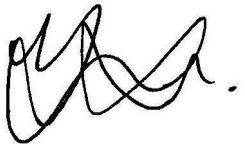
Vm 02000/4117

9. DATE OF FIRST AUTHORISATION

20 October 1993

10. DATE OF REVISION OF THE TEXT

July 2022



Approved: 05 September 2022