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
Oxytetracyline 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.

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

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)**

Although the product is well tolerated, occasionally a slight local reaction of a transient nature has been observed.

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**

None known.
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 25°C. 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
Northern Ireland

8. **MARKETING AUTHORISATION NUMBER**

Vm 02000/4117

9. **DATE OF FIRST AUTHORISATION**

20 October 1993

10. **DATE OF REVISION OF THE TEXT**

January 2020

Approved: 23 January 2020