Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 200 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Oxytetracycline (as Oxytetracycline Dihydrate)200mg

Excipient
Sodium Formaldehyde Sulphoxylate4mg

For a 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, pigs and piglets.

4.2 Indications for use, specifying the target species

Oxytetracycline is active against a wide range of Gram-positive and Gram-negative pathogenic bacteria, certain rickettsia and the larger viruses.Alamycin LA is indicated in the treatment of a wide range of common systemic, respiratory and local infections caused by or associated with organisms sensitive to oxytetracycline in cattle, sheep and pigs.

4.3 Contraindications

Do not use in animals suffering from hepatic or renal damage.
Do not use in animals with known hypersensitivity to Oxytetracycline.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Do not dilute Alamycin LA.

If concurrent treatment is administered, use a separate injection site.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals
None known.

4.6 Adverse reactions (frequency and seriousness)

Although 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 tetracycline during the period of tooth and bone development, including late pregnancy may lead to tooth discoloration.Alamycin LA can be safely administered during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts 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.If necessary repeat after 48 hours in sheep.

Maximum recommended dose at any one site:

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

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

Not applicable.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 28 days
Milk: 7 days

Pigs:
Meat and offal: 14 days

Sheep:
Meat and offal: 7 days
Milk: 6 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracyclines
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 receptor site on the messenger RNA ribosome complex.This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis.Alamycin LA is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate
Magnesium Oxide
Dimethylacetamide
Disodium Edetate
Ethanolamine
Water for Injections

6.2 Major incompatibilities

Do not mix the product with other 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.

6.5 Nature and composition of immediate packaging

Amber type II glass vials of 50 ml, and 100 ml with nitryl bungs and aluminium seals containing a clear solution for injection.
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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

January 2019