Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin 100 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Oxytetracycline Hydrchloride100mg/ml

Excipients:
Sodium Formaldehyde Sulphoxylate1.5mg/ml

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle
Sheep
Pigs

4.2 Indications for use, specifying the target species

Alamycin 10% Injection 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

Contraindicated in animals suffering from renal or hepatic damage and in animals with known hypersensitivity to Oxytetracycline.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

If the volume of product to be administered is greater than 20ml it should be divided and injected into two sites.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

The use of tetracycline during the period of tooth development, including late pregnancy may lead to tooth discoloration.Alamycin 10% Injection can be safely administered during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

Administer by intramuscular or slow intravenous injection in cattle, and by intramuscular injection in pigs and sheep.The recommended dosage is as follows:

Cattle:4 mg/kg (2ml per 50kg bodyweight), daily for 3-5 days.
Sheep:4-9 mg/kg (2-4.5ml per 50kg bodyweight), daily for 3-5 days.
Pigs:4-9 mg/kg (2-4.5ml per 50kg bodyweight), daily for 3-5 days.

It is recommendedthat, when the intravenous route is used in cattle, no more than two consecutive daily injections are administered.

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

Not applicable.

4.11 Withdrawal period(s)

Milk for human consumption must not be drawn from cows until at least 84 hours after the last treatment.(that is , from the 7th milking in cows milked twice

daily).Sheep and pigs may be slaughtered for human consumption only after 15 days from the last treatment.
Cattle may be slaughtered for human consumption only after 18 days from the last treatment.
Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use; Tetracyclines; Oxytetracycline.
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 amino-acyl transfer RNA to the receptor site on the messenger RNA ribosome complex.This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Chloride Dimethylacetamide
Ethanolamine
Citric Acid
Sodium Formaldehyde Sulfoxylate
Water for Injections

6.2 Major incompatibilities

Dilution with solutions of calcium salts will cause precipitation and must be avoided.

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 25^0C.
Protect from light.

6.5 Nature and composition of immediate packaging

Alamycin 100 mg/ml is a sterile aqueous antibiotic solution packaged in amber Type II glass vials of 50 ml and 100 ml sealed with nitryl rubber bungs and aluminium caps.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/015/001

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