Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin L.A. Veterinary

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Oxytetracycline (as Dihydrate) 200 mg

Excipient

Sodium Formaldehyde Sulphoxylate 2 mg

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, pigs and sheep.

4.2 Indications for use, specifying the target species

Antibiotic, treatment of sensitive microorganisms in cattle, pigs and sheep.

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

In case of contact with eyes or skin, wash immediately with water as irritation may occur.

Wash hands after use.

Take care to avoid accidental injection.

4.6 Adverse reactions (frequency and seriousness)

Although well tolerated, occasionally a slight local reaction of a transient nature has been observed. Hypersensitivity reactions, including anaphylaxis (sometimes fatal), have been reported very rarely.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

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 interaction

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.

Maximum recommended dose at any one site:

Cattle:	20 ml	
Pigs:	5.5 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: 35 days

Milk: 8 days

Pigs:
Meat and offal: 20 days

Sheep:
Meat and offal: 20 days
Milk: 8 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

2-Pyrrolidone
Povidone K12
Light Magnesium Oxide
Sodium Formaldehyde Sulphoxylate
Monoethanolamine
Hydrochloric Acid
Water for Injections

6.2 Incompatibilities

Do not mix the product with other medicinal products.

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials.

Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Store at a temperature below 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 Chlorobutyl 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
Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MANUFACRURER
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down, Northen Ireland
BT35 6JP
UK

8 MARKETING AUTHORISATION HOLDER
Comex Ltd.
Nablus Road No. 1
P.O.B. 19943, Jerusalem 97200

9 MARKETING AUTHORISATION NUMBER
080-95-92179-00

Revised in June 2023 according to MoH's guidelines.