1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 300 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

300 mg Oxytetracycline base (as Oxytetracycline dihydrate)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Magnesium Oxide	
Dimethylacetamide	
Sodium formaldehyde Sulphoxylate	4.0 mg
Water for Injections	

A clear dark amber liquid free from visible particles.

3. CLINICAL INFORMATION

3.1. Target species

Cattle, pigs and sheep.

3.2. Indications for use for each target species

For the treatment and control of conditions caused by, or associated with, organisms sensitive to oxytetracycline including:

Bordetella bronchiseptica
Actinomyces pyogenes
Erysipelothrix rhusiopathiae
Pasteurella spp.
Staphylococcus spp.
Streptococcus spp.
Certain mycoplasma, rickettsiae, protozoa and chlamydia.

The veterinary medicinal product may be used in the treatment and control of a wide range of common systemic, respiratory, urinary and local infections caused by oxytetracycline sensitive organisms. Specific indications for the veterinary medicinal product include:

pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, joint-ill, navel-ill, supportive therapy in bovine mastitis, ovine keratoconjunctivitis (pink-eye) and enzootic abortion in sheep.

3.3. Contraindications

Do not dilute the veterinary medicinal product.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4. Special warnings

None

3.5. Special precautions for use

Special precaution(s) for safe use in the target species:

If concurrent treatment is administered use a separate injection site.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

Target species: Cattle, sheep, pigs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction [1] Hypersensitivity reaction[2] Anaphylaxis[2]

[1] Swelling and/or hardness may be observed for up to 1 to 3 weeks.
[2] Sometimes fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

Pregnancy and lactation:

The use of veterinary medicinal product during the period of tooth and bone development, including late pregnancy, may lead to discoloration. The veterinary medicinal product can be safely administered during lactation.

3.8. Interaction with other medicinal products and other forms of interaction

None known.

3.9. Administration route and dosage

Deep intramuscular injection.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The veterinary medicinal product can be administered at the standard dose of 20 mg/kg for 3 to 4 days duration of activity for the treatment and control of conditions caused by organisms sensitive to the action of oxytetracycline. The veterinary medicinal product can be administered at the high dose of 30 mg/kg for the treatment and control of respiratory infections in sheep, pigs and cattle.

Cattle, sheep and pigs:	
Standard dose -	20 mg/kg (1ml/15kg)
High dose -	30 mg/kg (1ml/10kg)
Maximum recommended dosage at one site:	
Cattle:	10 ml
Sheep:	5 ml
Pigs:	10 ml
Piglets:	1 day old: 0.2 ml
	7 days old: 0.3 ml
	14 days old: 0.4 ml
	21 days old: 0.5 ml
	over 21 days of age: 1 ml/10 kg

3.10. Symptoms of overdose (and where applicable, emergency procedures, antidotes), if necessary

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12. Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment.
Milk for human consumption must not be taken during treatment.

Cattle:
Meat and offal: 35 days.

Milk: 10 days.

Pigs:
Meat and offal: 28 days.

Sheep:
Meat and offal: 28 days.
Milk: 8 days.

4. PHARMACOLOGICAL INFORMATION

4.1. ATCvet Code: QJ01AA06

4.2. Pharmacodynamics

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 the amino acids to the elongating peptide chain, inhibiting protein synthesis.

5. PHARMACEUTICAL PARTICULARS

5.1. Major incompatibilities

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

5.2. 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.

5.3. Special precautions for storage

Store below 25 C.
Protect from light.
Keep the vial in the outer carton.

5.4. Nature and composition of immediate packaging

'Immediate packaging:

- 100 ml, 250 ml and 500 ml amber type I glass vials sealed with bromobutyl bungs and aluminium caps.

Outer packaging and sales presentations:

- 100 ml vial is contained in a carton.
- 250 ml and 500 ml vials contained in plastic bottle protectors.'

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/039/001

8. DATE OF FIRST AUTHORISATION

10/02/1994

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

15/04/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).