

SUMMARY OF PRODUCT CHARACTERISTICS
Veterinarian Prescription only medicine
For animal use only

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICIN

Alamycin LA Veterinary, Solution for injection, IM

2. ACTIVE INGREDIENTS

1 ml of the medicinal product contains:

Oxytetracyclin 200 mg (as Oxytetracyclin Dihydrate 216 mg)

For a full list of excipients, see section 13 "further information"

3. Indications for use

Antibiotic: treatment of sensitive microorganisms in Cattle, Sheep and Pigs.

In use for the following infections:

- Atrophic rhinitis caused by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida*.
- Navel/joint ill caused by *Treuperella pyogenes*, *E. coli* or *Staphylococcus aureus*.
- Mastitis caused by *Corynebacterium pyogenes*, *E. coli*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus uberis*.
- Metritis caused by *E. coli* or *Streptococcus pyogenes*.
- Pasteurellosis and infections of the respiratory tract caused by *Pasteurella haemolytica* and *Pasteurella multocida*.
- Septicaemia caused by *Salmonella dublin* and *Streptococcus pyogenes*.
- Erysipelas caused by *Erysipelothrix rhusiopathiae*.

Therapeutic Group: Antibiotic

4. Contraindications

Do not use in Cats, Dogs and Horses

Do not dilute the product

Do not use in animals suffering from hepatic or renal damage.

Do not use in animals with known hypersensitivity to Oxytetracycline.

5. Adverse reactions (frequency and seriousness)

Occasionally a slight local reaction of a transient nature has been observed.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.it) which refers to the online form for reporting adverse events, or by entering the link:

<https://sideeffects.health.gov.il/>

6. Target Species:

Cattle, Sheep, Pigs

7. 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

8. How to use the preparation:

The recommended use is in a single dose injection

In the absence of compatibility studies, this veterinary product should not be mixed with other veterinary medicinal products

9. Withdrawal period

Cattle:

Meat and offal: 35 days

Milk: 8 days

Pigs:

Meat and offal: 20 days

Sheep:

Meat and offal: 20 days

Milk: 8 days

10. Special warnings and precautions for use:

- Special precautions for use in animals:

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

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

Wash your Hands after use.

In case of contact with eyes or skin rinse immediately with water to prevent irritation.

Take care to avoid accidental injection.

- 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
- Interaction with other medicinal products and other forms of interaction:
None known.
- Overdose:
In case of symptoms of overdose, symptomatic treatment should be given.

11. **Storage instructions**

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
- Storage conditions: Store below 25°C. Protect from light.
- After first opening of the packaging can be used up 28 days. remains of the product should be discard after 28 days.
- After using the vial, exposing the contents to air, the color of the solution may darken but the efficacy of the product does not change.

12. **Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of sewage.

13. **FURTHER INFORMATION:**

In addition to the active ingredient the product also contains:

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

Pharmaceutical form:

A clear amber solution

Packaging size:

- 100ml and 50ml glass vials

Not all pack sizes may be marketed.

Registration holder: :Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200

Manufacturer: Norbrook Laboratories Limited , Station Works, Newry, Northern

Ireland, BT35 6JP, UK

Product registration number: 080-95-92179-00

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