Veterinary Medicine User Leaflet

Veterinarian Prescription only medicine

For animal use only

1. NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE:
Alamycin LA Veterinary, Solution for Injection, 200 mg/ml

2. ACTIVE INGREDIENT:
Each 1 ml of the medicine contains:
Oxytetracycline (as Dihydrate) *200 mg*

The medicine also contains the excipient:
Sodium Formaldehyde Sulphoxylate 2 mg

For a full list of excipients, see section 13 “further information”.

3. Indications for use:
Antibiotic treatment of sensitive microorganisms in cattle, pigs and sheep.
Therapeutic Group: Antibiotic.

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

5. Adverse reactions:
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.

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.il) which refers to the online form for reporting adverse events, or by entering the link:
https://sideeffects.health.gov.il/

6. Target Species:
Cattle, pigs and sheep

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.

8. How to use the product:
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

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. Warnings:
- Special precautions regarding the use of the medicine for the target animal:
  None.
- Special safety precautions regarding the use of the medicine 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 product to the 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.
- Additional precautions:
  None.
- 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.
- Interactions with other medicinal products and other forms of interactions:
  None known.
- Overdose:
  Not applicable.
- Incompatibilities:
  Do not mix the product with other medicinal products.

11. Storage instructions:

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants and thereby prevent poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of the month.
- Storage conditions:
  Store at a temperature below 25°C. Protect from light.
- After first opening of the package the product should be used up within 28 days. Remains of the product should be discarded after 28 days.
- After using the vial and 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 of 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, Monoethanolamine, Hydrochloric Acid, Water for Injection.
- Pharmaceutical form:
  A clear amber solution.
- Packaging sizes:
  Amber type II glass vials of 50 ml and 100 ml with Chlorobutyl bungs and aluminium seals.
  Not all pack sizes may be marketed.

- **Registration holder and address:**
  Comex Ltd., Nablus Road No.1, POB 19943, Jerusalem 97200

- **Manufacturer and address:**
  Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, Northern Ireland, UK

Revised in June 2023 according to MoH's guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 080-95-92179-00