

This leaflet has been reviewed and approved by the MoH: 6.2010

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

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICIN

Alamycin Aerosol Veterinary, topical spray

2. ACTIVE INGREDIENTS

Oxytetracycline Hydrochloride 32.1 Mg/MI

Each 140g aerosol can contain:

Oxytetracycline Hydrochloride 5 gr (3.6% w/w)

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

3. Indications for use

Oxytryccline in indicated for the treatment in wide range of gram positive and gram negative bacterial pathogens. Alamycin Aerosol is indicated for the treatment of foot rot and topical infections caused by organisms sensitive to oxytetracycline in sheep.

Therapeutic Group: Tetracyclin antibiotic

4. Contraindications

Do not use in animals with known hypersensitivity to the active substance.

5. Adverse reactions (frequency and seriousness)

None known.

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:

Sheep

7. Amounts to be administered and administration route

For Topical use.

Foot rot: Before spraying, the infected area should be cleaned and hooves should be pared.

8. How to use the preparation:

Holding the can upright, spray at a distance of 15-20 cm away for a few seconds or until the area is covered.

Treated sheep should be allowed to stand on dry ground for one hour before returning to pasture.

9. **Withdrawal period**

Meat: 0 days.

Milk: 0 days.

In the case of forced slaughter, the treated area should be removed and not used for human consumption.

10. **Special warnings and precautions for use:**

- Special precautions for use in animals:

Keep away from the animal eyes.

For external use only.

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

Keep away from eyes.

Avoid contact with the skin.

Avoid inhalation.

Use only in a well ventilated area.

Wash hands after use.

Wear protective gloves/protective clothing/eye protection/face protection.

Extremely flammable aerosol.

Pressurized container: may burst in heat.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

Do not spray on an open flame or other ignition source.

Pressurized container: Do not pierce or burn, even after use.

Protect from sunlight.

Do not expose to temperatures exceeding 25 °C. Keep out of the reach of children.

Toxic in swallowing, toxic in contact with the skin, toxic in inhalation, causes severe irritation to the eyes.

May cause drowsiness or dizziness.

Suspected of damaging fertility or the unborn child.

In the case of ingestion, immediately contact the National Institute for Poison Information at the Rambam Health Care Campus or to the doctor.

In the case of contact with the eyes, carefully wash with water for several minutes. Remove contact lenses if any and if they can be removed easily and continue to wash.

Keep out of reach or sight of children.

- Use during pregnancy, lactation or lay

No adverse effects or foetal abnormalities have been observed following the administration of oxytetracycline aerosol during pregnancy and lactation.

- Interaction with other medicinal products and other forms of interaction:

None known.

- Overdose:

Not applicable.

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.
- Pressurized container: Protect from sunlight. Do not expose to temperatures exceeding 25 °C.
- After first opening of the packaging can be used up to exp. Date written on the package.

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:

Magnesium Chloride; Patent Blue; Polypropylene Glycol; Purified Water; Monoethanolamine; Povidone; Isopropyl Alcohol: Methanol 1:1

Pharmaceutical form:

- A blue opaque solution, Cutaneous Spray.

Packaging size:

- 140g pressurised aluminium can filled with nitrogen gas (no Oxygen)

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: 081-27-92217-00

Must be prescribed by a veterinarian	For Veterinary Use Only
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Caution! Extremely flammable, keep away from fire

Danger! Not for eating!