

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin Aerosol Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Oxytetracycline Hydrochloride 32.1 mg/ml (equivalent to 3.21% w/v)
Each 140g aerosol can contains 5g Oxytetracycline Hydrochloride (equivalent to 3.6% w/w).

Excipients

Patent Blue V (E 131) 0.33% w/w as a marker dye

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous spray solution
A blue opaque solution.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

Oxytetracycline is 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 Oxytetracycline-sensitive organisms in sheep.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special Warnings for Each Target Species

None.

4.5 Special Precautions for Use

Special Precautions for use in animals

For external use only.

Keep away from the animal's eyes

Special precautions to be taken by the person administering the product to the animals

Keep away from eyes.

Avoid contact with skin. Avoid inhaling vapours.

Must be used 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.

4.6 Adverse reactions (frequency and seriousness):

None.

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 product can be safely administered to pregnant and lactating animals.

4.8 Interactions with other medicinal products and other forms of interaction

None.

4.9 Amount to be administered and administration route

For the treatment of foot rot, clean the affected area prior to administration. Wounds should be cleaned prior to administration. Shake the can before use. Spray for a few seconds or until the lesion is adequately covered.

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

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)

Not applicable.

4.11 Withdrawal periods

Sheep:

Meat – Zero days

Milk – Zero hours

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATCvet Code: QD06AA03

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 acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)

Povidone K17

Polypropylene Glycol

Magnesium Chloride

Purified Water

Monoethanolamine

Isopropyl Alcohol : Methanol (1:1)

6.2 Incompatibilities

None Known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Aluminium cans with valves caps and actuators (140g pack size).
The propellant is Nitrogen (oxygen-free).

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MANUFACTURER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION HOLDER

Abic Veterinary Products Ltd.
2 Hanegev Street
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7019900

9. MARKETING AUTHORISATION NUMBER

081-27-92217-00

Revised in January 2025 according to MoHs guidelines.