1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin Aerosol 3.2% w/v Cutaneous Spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 140 g aerosol can contains:

Active substance:
Oxytetracycline 3.2 % w/v
(as oxytetracycline hydrochloride)
Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent Blue V (E131)	0.3 % w/v
Magnesium Chloride	
Povidone	
Propylene Glycol	
Ethanolamine	
Purified Water	
Isopropyl Alcohol	
Methyl Alcohol	

A blue opaque solution.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for topical use in the treatment of foot rot in sheep and topical infections caused by organisms sensitive to oxytetracycline in cattle, sheep and pigs.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings for each target species

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only.

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

Keep away from eyes.
Use only in a well-ventilated area.
Avoid inhalation and contact with skin.
Wash hands after use.
Wash any splashes immediately.
Do not spray on a naked flame or any incandescent material.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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:

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Foot Rot
For the treatment of foot rot, clean the affected area prior to administration. Holding the can upright, spray at a distance of 6 - 8 inches away for a minimum of 5 seconds or until the area is covered.

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

Wounds :
Wounds should be cleaned prior to application.

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

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 periods

Meat and offal: Zero days

Milk : Zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code: QD06AA03.

4.2 Pharmacodynamics

Oxtetracycline 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.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

5.3 Special precautions for storage

Store below 25°C.
Protect from direct sunlight.
Pressurised container, do not expose to temperatures above 50ºC.

5.4 Nature and composition of immediate packaging

140 g pressurised aluminium can with valves, caps and actuators.

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

Do not incinerate or puncture the can even when empty.

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)

VPA22664/014/001

8. DATE OF FIRST AUTHORISATION

01/10/1998

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

05/06/2024

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).