SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin Aerosol 3.58% w/w cutaneous spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Each 140g aerosol can contains 5g Oxytetracycline Hydrochloride (equivalent to 3.58% 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*:

Cattle, sheep and pigs

4.2 *Indications for use, specifying the target species:*

Alamycin Aerosol is indicated for the treatment of foot rot in sheep and topical infections caused by organisms sensitive to oxytetracycline in cattle, sheep and pigs.

4.3 *Contraindications:*

None.

4.4 *Special Warnings for Each Target Species:*

None.

4.5 *Special Precautions for Use:*

Special Precautions for use in animals:
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.
Wash hands after use.
Do not spray on a naked flame or any incandescent material.
Highly flammable.
Must be used in a well ventilated area.
Do not smoke when using this product.

4.6 ***Adverse reactions (frequency and seriousness):***

None.

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, the hooves should be cleaned and pared 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:***

Cattle:	Sheep:	Pigs:
Meat – Zero days	Meat – Zero days	Meat – Zero days
Milk – Zero hours	Milk – Zero hours	

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)
Magnesium Chloride Hexahydrate
Povidone K17
Propylene Glycol
Ethanolamine
Water Purified
Isopropyl Alcohol
Methyl Alcohol

6.2 ***Incompatibilities:***

None Known.

6.3 ***Shelf-life:***

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

6.4 ***Special precautions for storage:***

Pressurised container, protect from sunlight and do not expose to temperatures above 50°C.
Do not pierce or burn, even after use.
Do not store above 25ºC.

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. **MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited
Station Works
Camlough Road
NEWRY
Co. Down, BT35 6JP
Northern Ireland

8. **MARKETING AUTHORISATION NUMBER**

Vm 02000/4053

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

5th June 1984/5th June 2004

10. **DATE OF REVISION OF THE TEXT**

February 2008