Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin Aerosol 3.2 %w/v Cutaneous Spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 140g aerosol can contains:

Active Substance

Oxytetracycline (as oxytetracycline hydrochloride)	3.2	% w/v

Excipient

Patent Blue V (E131)	0.3	% w/v

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 topical use in the treatment of foot rot in sheep and topical infections caused by organisms sensitive to oxytetracycline in cattle, sheep and pigs.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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.

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

Not applicable.

4.11 Withdrawal period(s)

Meat : Zero days

Milk : Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibiotics for topical use; Oxytetracycline.
ATCvet Code: QD06AA03.

5.1 Pharmacodynamic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Magnesium chloride

Povidone
Propylene Glycol
Ethanolamine
Water for Injections
Isopropyl Alcohol
Methyl Alcohol

6.2 Major 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^{o}C.
Store below 25^{o}C.

6.5 Nature and composition of immediate packaging

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

6.6 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.

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

January 2020