1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terramycin Aerosol Spray for sheep.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each aerosol can contains:

Active substance:
Oxytetracycline hydrochloride 4.0 g

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)	0.2 g
n-Butane	62.8 g
Polysorbate 80	
Isopropyl Alcohol	

A blue, fine mist spray.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

General: for the treatment and control of topical infections caused by, or associated with, organisms sensitive to oxytetracycline.

Specific: treatment of foot rot and scald.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not spray in or near the eyes.

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

Use only in a well-ventilated area and avoid inhaling the spray.
Wash any splashes immediately.
Operator should wear impervious gloves.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Extremely flammable. Do not spray on naked flame or any incandescent material.

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:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cutaneous use.
Shake well before use.
For ovine foot conditions a spray-time of 3-5 seconds should be sufficient.
Clean the affected area prior to administration.
Treatment should be repeated weekly when necessary.

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

None known.

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 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QD06AA03.

4.2 Pharmacodynamics

Pharmacotherapeutic group: Dermatologicals, antibiotics for topical use, tetracycline and derivatives.

Oxytetracycline is a member of the tetracycline group of antibiotics and is produced by fermentation of *Streptomyces rimosus*. It possesses broad spectrum antimicrobial activity against a wide range of gram +ve and gram -ve bacteria, certain mycoplasmas, protozoa, rickettsiae and *Chlamydia*.

Oxytetracycline is bacteriostatic and acts by inhibiting protein synthesis within the cell.
When given topically oxytetracycline comes into direct contact with bacteria on the skin and in superficial lesions on external body surfaces. The marker dye indicates the extent of the treated area.

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

Do not store above 25 °C.
The container is pressurised, do not expose to heat or sunlight.

5.4 Nature and composition of immediate packaging

Pressurised lacquered aluminium aerosol can containing in each 150 ml pack 4 g oxytetracycline hydrochloride incorporating a blue marker dye. A special valve (type PCA 39 PV) is incorporated enabling the product to be operated efficiently in the upright and inverted positions.

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

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.

Do not puncture can.

Do not burn.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10387/076/001

8. DATE OF FIRST AUTHORISATION

09/12/2013

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

13/11/2024

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).