

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terramycin Aerosol Spray 3.92% w/w cutaneous spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 150 ml can contains:

Active substance:

Oxytetracycline hydrochloride 4.0g (equivalent to 3.92% w/w)

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)	0.2g
Polysorbate 80	
Isopropyl Alcohol	
Butane	

A blue, fine mist spray.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

For the treatment and control of topical infections caused by, or associated with, organisms sensitive to oxytetracycline. Includes digital dermatitis in cattle; foot rot and scald in sheep.

3.3 Contraindications

None.

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 eyes.

For external use only.

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

People with known hypersensitivity to oxytetracycline should avoid contact with the veterinary medicinal product.

Use only in a well-ventilated area.

Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.

Wash any splashes immediately. Wash hands after use.

Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Do not smoke when using this product.

EXTREMELY FLAMMABLE.

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:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

May interact with solutions containing metal salts.

3.9 Administration routes and dosage

Topical administration only.

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)

Overdosing should pose no problems.

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

Cattle and sheep (meat and offal): Zero days.

Cattle (milk): Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QD06AA03

Antibiotics and chemotherapeutics for dermatological use.

Antibiotics for topical use.

Tetracycline and derivatives.

4.2 Pharmacodynamics

Oxytetracycline 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.

4.3 Pharmacokinetics

When administered topically, oxytetracycline absorption is negligible; it 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.
Store in a dry place.

Pressurised container: Protect from sunlight and do not expose to heat.

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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5175

8. DATE OF FIRST AUTHORISATION

8 February 1989

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

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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Gavin Hall