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

Active ingredient
Oxytetracycline hydrochloride 3.92% w/w

Excipient
Patent Blue V (E131) 0.192% w/w

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep.

4.2 Indications for use, specifying the target species

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

Specific: treatment of digital dermatitis in cattle and treatment of foot rot and scald in sheep.

4.3 Contraindications

None.

4.4 Special warnings for each target species

For external use only.
Do not spray in or near the eyes.

4.5 Special precautions for use

(i) Special precautions for use in animals

Do not spray in or near eyes.
Use only in a well ventilated area.
For external use only.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Use only in a well-ventilated area.
Wash any splashes immediately.
Operator should wear impervious gloves.
Wash hands after use.
Extremely flammable.
Do not pierce or burn, even after use.
Do not spray on a naked flame or any incandescent material.
Keep away from sources of ignition – No smoking.
People with known hypersensitivity to oxytetracycline should avoid contact with the product.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Suitable for use in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Any solution containing metal salts.

4.9 Amounts to be administered and administration route

Shake can before use and apply topically. 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.

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

Overdosing should pose no problems.

4.11 Withdrawal periods

Cattle:	Meat	- Zero days
	Milk	- Zero days
Sheep:	Meat	- Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Antibiotics and chemotherapeutics for dermatological use
Antibiotics for topical use
Tetracycline and derivatives

ATC Vet Code: QD06AA03

Pharmadynamic properties

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.

Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Polysorbate 80
Isopropyl Alcohol
Butane

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

Do not store above 25°C.
Store in a dry place.

Pressurised container: Protect from sunlight and do not expose to temperatures exceeding 50°C.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 60021/3022

9. DATE OF FIRST AUTHORISATION

8 February 1989

10. DATE OF REVISION OF THE TEXT

November 2024

Gavin Hall
Approved 15 November 2024