Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Terramycin Aerosol Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

per aerosol can:

Active Substance

Oxytetracycline hydrochloride 4.0g
Excipients

Patent Blue V (E131) 0.2g
n-Butane 62.8g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Spray, suspension.
A blue, fine mist spray.

4 CLINICAL PARTICULARS

4.1 Target Species

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 foot rot and scald.

4.3 Contraindications

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

4.4 Special warnings for each target species

Do not spray in or near the eyes.

4.5 Special precautions for use

Special precaution(s) for use in animals
Do not spray in or near eyes.

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

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 interactions

None known.

4.9 Amounts to be administered and administration route

For topical administration only.
Shake well 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 period(s)

Meat and offal: zero days.
Milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, antibiotics for topical use, tetracycline and derivatives.
ATCvet code: QD06AA03.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent blue V (E131)
Polysorbate 80
Isopropyl Alcohol
n-Butane

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

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

6.5 Nature and composition of immediate packaging

Pressurised lacquered alumininium 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.

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

Do not puncture can.

Do not burn.

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/076/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1988
Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

March 2020