SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycare 3.6 %w/w Cutanous Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each 140g aerosol can contain's:

5g Oxytetracycline Hydrochloride 3.6% w/w

Excipients:

Patent Blue V (E 131) 0.33% w/w as a marker dye

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

Oxycare Aerosol is indicated for the treatment of foot rot in sheep and topical infections caused by organisms sensitive to oxytetracycline in cattle, sheep and pigs.

4.3 Contraindications

None

4.4 Special Warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possiable, thearpy should be based on local (regional, farm level) epidermiological information about susceptibility of the target bacteria.

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

Keep away from eyes.
Avoid contact with skin.
Avoid inhaling vapours.
Wash hands after use.
Do not spray on a naked flame or any incandescent material.
Highly flammable
Must be used in a well ventilated area
Do not smoke when using this product.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

For the treatment of foot rot, the hooves should be cleaned and pared prior to administration. Wounds should be cleaned prior to administration. Shake the can before use. Spray for a few seconds or until the lesion is adequately covered

Treated sheep should be allowed to stand on dry ground for one hour before returning to pasture.

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

Not applicable.

4.11 Withdrawal period

Meat –Zero days
Milk – Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotics and chemotherapeutics for dermatological use, Antibiotics for topical use, Tetracycline and derivatives

ATC Vet Code: QD06AA03

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in a wide range of 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 Hexahydrate,
Povidone K17,
Propylene Glycol,
Ethanolamine (for pH adjustment),
Methanol/ Isopropyl Alcohol,
Water Purified.

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

Pressurised container, protect from sunlight and do not expose to temperatures above 50°C.
Do not pierce or burn, even after use.
Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

Aluminium cans containing 140g of product with valves caps and actuators.
Aerosol bag on valve assembly, capable of delievering 10g to 15g of product per 5 seconds
The propellant is Nitrogen (oxygen-free).

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

Any unused veterinary medicinal product or waste materials derived from such veterianry medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

8. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4164

9. DATE OF FIRST AUTHORISATION

30th March 1998

10. DATE OF REVISION OF THE TEXT

July 2010

DISTRIBUTED BY
Animalcare Ltd
10 Great North Way
York Business Park
Nether Poppleton
York
YO26 6RB