PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycare 3.6 % w/w Cutaneous Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

140g Aerosol containing:

Oxytetracycline hydrochloride 5g (equivalent to 3.6% w/w) and a blue marker dye

3. PHARMACEUTICAL FORM

Cutaneous Spray

4. PACKAGE SIZE

140g

5. TARGET SPECIES

Cattle,

Sheep,

Pigs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spray for a few seconds or until the lesion is adequately covered.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat – Zero days

Milk – Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

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

Shake the can before use.

Keep away from eyes.

Avoid inhalation and contact with skin.

Wash hands after use.

Must be used in a well ventilated area.

Do not smoke when using this product.

FOR EXTERNAL USE ONLY

Further information: see package leaflet.

Highly flammable.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Pressurised container.

Do not pierce or burn, even after use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For Animal Treatment Only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4164

17. MANUFACTURER'S BATCH NUMBER

Bn.: D.O.M.:

Distributed by: Animalcare Ltd 10 Great North Way York YO26 6RB

PACKAGE LEAFLET FOR: OXYCARE 3.6% w/w CUTANEOUS SPRAY SOLUTION

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufactured by: Norbrook Laboratories Limited Station Works Newry Co. Down BT35 6JP Northern Ireland

Distributed by: Animalcare Ltd 10 Great North Way York YO26 6RB

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycare 3.6 % w/w Cutaneous Spray Solution

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A blue coloured aerosol cutaneous spray containing 5g oxytetracycline hydrochloride per 140g can (3.6% w/w)

4. INDICATION(S)

Oxytetracycline is active against a wide range of Gram-positive and Gramnegative pathogenic bacteria.

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

7. TARGET SPECIES

Cattle, Sheep, Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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.

10. WITHDRAWAL PERIOD(S)

Meat - Zero days.

Milk - Zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

Protect from sunlight and do not expose to temperatures above 50°C.

Pressurised container.

Do not pierce or burn even after use

12. SPECIAL WARNING(S)

Keep away from eyes. Avoid contact with skin. Wash hands after use. Avoid inhaling vapours. Do not spray on a naked flame or any incandescent material.

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Pressurised container. Do not pierce or burn even after use. For external use only. Highly flammable. Must be used in a well ventilated area. Do not smoke when using this product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2013

15. OTHER INFORMATION

Package Quantities: Aerosol of 140g

Marketing Authorisation Number: Vm 02000/4164

For Animal Treatment Only.

POM-V

To be supplied only on veterinary prescription.

Approved: 07/08/2017