SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycare 10% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s)	**% w/v**
Oxytetracycline Hydrochloride	10.00

Excipient(s)

Sodium Formaldehyde Sulphoxylate Dihydrate	0.15

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A clear yellow amber solution.

4. CLINICAL PARTICULARS

4.1 *Target species*:

Cattle
Pigs

4.2 *Indications for use, specifying the target species:*

For the treatment of diseases caused by or associated with organisms sensitive to oxytetracycline in cattle and pigs.

4.3 *Contraindications:*

Do not use in animals suffering from renal or hepatic damage.

Do not use in animals with known hypersensitivity to oxytetracycline or any of the excipients.

4.4 *Special Warnings for Each Target Species:*

None

4.5 ***Special Precautions for Use:***

i) Special Precautions for use in animals:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Official and local antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to oxytetracycline.

It is important to administer intravenous injections of the product slowly.

ii) Special precautions to be taken by the person administering the product to the animals:

Take care to avoid accidental injection. Wash hands after use. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

4.6 ***Adverse reactions (frequency and seriousness):***

General toxicity is low although collapse has been reported with tetracyclines in weak or debilitated animals.

Other adverse reactions to oxytetracycline that have been observed include gastrointestinal disorders and, less frequently, allergic and photosensitivity reactions.

Tooth discolouration can occur if oxytetracycline is administered to young animals.

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4.7 ***Use during pregnancy, lactation or lay:***

Oxytetracycline can retard skeletal growth of the fetus if administered during pregnancy.

The use of tetracyclines during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

Tetracyclines are excreted in milk.

The product should only be used according to the benefit/risk assessment by the responsible veterinary surgeon.

4.8 ***Interactions with other medicinal products and other forms of interaction:***

Dilution with calcium salts will cause precipitation and should be avoided.

Oxytetracycline may interfere with the action of bactericidal antimicrobials, such as penicillins and cephalosporins, and therefore they should not be used simultaneously.

4.9 ***Amount to be administered and administration route:***

By intramuscular or slow intravenous injection

Cattle; 1.5-4.0 mg/kg bodyweight daily for 3 to 5 days
Pigs: 2.0-9.0 mg/kg bodyweight daily for 3 to 5 days

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Maximum dose volume for cattle should not exceed 10 ml per site.
Maximum dose volume for pigs should not exceed 5 ml per site.

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

There is no known specific antidote. If signs of possible overdose occur, treat the animal symptomatically.

4.11 ***Withdrawal periods:***

Cattle:
Meat & Offal: 16 days
Milk: 84 hours

Pigs:
Meat & Offal: 11 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic
ATCvet Code: QJ01 AA06

5.1 ***Pharmacodynamic properties:***

Oxytetracycline is active against a wide range of Gram positive and Gram negative pathogenic bacteria, and certain Rickettsia. Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in 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 amino-acyl transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

5.2 Pharmacokinetic particulars:

Oxytetracycline is widely distributed in the body, including to the kidneys, liver, lungs and muscle, though only small quantities are distributed to the CSF. The placenta is readily passed by oxytetracycline and concentration in the fetal blood may reach that of the maternal circulation. Oxytetracycline apparently is not metabolised *in vivo* and is eliminated primarily unchanged, via glomerular filtration. It is also excreted into the GI tract via both biliary and non-biliary routes and may become inactive after chelation with faecal material.

6. PHARMACEUTICAL PARTICULARS

6.1 *List of excipients:*

Sodium Formaldehyde Sulphoxylate Dihydrate
Magnesium Chloride Hexahydrate
Dimethylacetamide
Citric Acid Monohydrate
Ethanolamine (for pH adjustment)
Water for Injection

6.2 *Incompatibilities:*

None known.

6.3 *Shelf-life:*

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days.

6.4 *Special precautions for storage:*

Do not store above 25ºC.
Protect from light.
Once broached, use vial within 28 days.
Discard unused material.

6.5 ***Nature and composition of immediate packaging:***

50ml and 100ml amber glass (Type II) vials with bromobutyl rubber bungs, secured with aluminium caps.
Not all pack sizes may be marketed.

6.6 ***Special precautions for the disposal of unused veterinary medicinal products 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

Norbrook Laboratories Limited

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4284

9. DATE OF FIRST AUTHORISATION

19th July 2005

10. DATE OF REVISION OF THE TEXT

October 2014

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