

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Oxycare 200 mg/ml LA Solution for Injection for Cattle, Sheep and Pigs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains

#### **Active substance**

Oxytetracycline 200 mg

(Equivalent to Oxytetracycline Dihydrate 216 mg)

#### **Excipients**

Sodium Formaldehyde Sulfoxylate (2 mg)

For the full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Solution for injection.

A clear amber solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle, sheep and pigs.

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

The product is indicated for use in cattle, sheep and pigs in the treatment of:

- Atrophic rhinitis caused by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida*.
- Navel/joint ill caused by *Trueperella pyogenes*, *E. coli* or *Staphylococcus aureus*.
- Mastitis caused by *Corynebacterium pyogenes*, *E. coli*, *Staphylococcus aureus*, *Streptococcus agalactiae* or *Streptococcus uberis*.
- Metritis caused by *E. coli* or *Streptococcus pyogenes*.
- Pasteurellosis and infections of the respiratory tract caused by *Mannheimia haemolytica* and *Pasteurella multocida*.
- Septicaemia caused by *Salmonella dublin* and *Streptococcus pyogenes*.
- Erysipelas caused by *Erysipelothrix rhusiopathiae*.

The product can also be used in the control of enzootic abortion in sheep.

#### **4.3 Contraindications**

Do not use in horses, dogs, cats.  
Do not use in animals suffering from hepatic or renal damage.

#### **4.4 Special Warnings for Each Target Species**

None.

#### **4.5 Special Precautions for Use**

i. Special Precautions for use in animals

Do not dilute the product.

If concurrent treatment is administered, use a separate injection site.

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.

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

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

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

Wash hands after use. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

Take care to avoid accidental injection

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

Although the product is well tolerated, occasionally a slight local reaction of a transient nature has been observed.

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

The use of oxytetracycline during the period of tooth and bone development, including late pregnancy may lead to tooth discoloration, the product can be safely administered to lactating animals.

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

None known.

#### 4.9 Amount to be administered and administration route

The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. The product is recommended for a single administration only.

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

Maximum recommended dose at any one site:

Cattle :	20ml
Pigs :	10ml
Sheep:	5ml
Piglets:	1 day 0.2ml
	7 days 0.3ml
	14 days 0.4ml
	21 days 0.5ml
	Over 21 days 1.0 ml/10kg.

#### 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 and offal – 41 days  
Milk – 8 days

Sheep: Meat and offal – 24 days  
Milk – 7 days

Pigs: Meat and offal – 20 days

### 5. PHARMACOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Antibiotic

**ATCvet Code:** QJ01AA06

#### 5.1 Pharmacodynamic properties

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 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. The product is

specifically formulated to provide a prolonged action resulting in sustained antibacterial activity.

Oxytetracycline had been shown to be effective *in vitro* against the following bacterial species: *Bordetella bronchiseptica*, *Corynebacterium pyogenes*, *Erysipelothrix rhusiopathiae*, *Escherichia coli*, *Histophilus somni*, *Pasteurella haemolytica*, *Pasteurella multocida*, *Salmonella dublin*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus faecalis*, *Streptococcus pyogenes* and *Streptococcus uberis*.

## **5.2 Pharmacokinetic properties**

Blood levels persist for at least 4 days after administration by the intramuscular route. Maximum blood levels are achieved between 4 and 8 hours following intramuscular administration.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium formaldehyde sulfoxylate  
Magnesium Oxide Light  
2-Pyrrolidone  
Povidone K12  
Monoethanolamine  
Hydrochloric Acid  
Water for Injections

### **6.2 Major 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 25°C. Protect from light.

Following withdrawal of the first dose, use the product within 28 days.

Discard unused material

When the vial has been broached and contents exposed to air, the solution may darken but the potency will be unchanged.

**6.5 Nature and composition of immediate packaging**

Amber type II glass vials of 50 ml and 100 ml, sealed with Chlorobutyl Rubber Bungs and aluminium seal.

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  
Station Works  
Camlough Road  
Newry  
Co. Down  
BT35 6JP  
Northern Ireland

**8. MARKETING AUTHORISATION NUMBER**

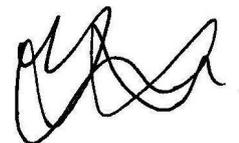
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**9. DATE OF FIRST AUTHORISATION**

30 April 1998

**10. DATE OF REVISION OF THE TEXT**

January 2020

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved: 23 January 2020