# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Maxoject LA 200mg/ml Solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Oxytetracycline (as Oxytetracycline Dihydrate) 200 mg

Excipient

Sodium Formaldehyde Sulphoxylate 2 mg

For a 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, pigs and piglets.

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

Oxytetracycline is active against a wide range of Gram-positive and Gram-negative pathogenic bacteria, certain rickettsia and the larger viruses. Maxoject LA is indicated in the treatment of a wide range of common systemic, respiratory and local infections caused by or associated with organisms sensitive to oxytetracycline in cattle, sheep and pigs.

### 4.3 Contraindications

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

Do not use in animals with known hypersensitivity to Oxytetracycline.

### 4.4 Special warnings for each target species

None.

**4.5 Special precautions for use**

**Special precautions for use in animals**

Do not dilute Maxoject LA.

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

**Special Precautions to be taken by the Person Administering the Medicinal Product to Animals**

In case of contact with eyes or skin, wash immediately with water as irritation may occur.

Wash hands after use.

Take care to avoid accidental injection.

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

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

Hypersensitivity reactions, including anaphylaxis (sometimes fatal), have been reported very rarely.

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

The use of tetracycline during the period of tooth and bone development, including late pregnancy may lead to tooth discoloration. Maxoject LA can be safely administered during lactation.

**4.8 Interaction with other medicinal products and other forms of interaction**

None known.

**4.9 Amounts 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.

Maximum recommended dose at any one site:

| | | |
|---|---|---|
| Cattle: | 20 ml | |
| Pigs: | 5.5 ml | |
| Sheep: | 5 ml | |
| Piglets: | 1 day | 0.2 ml |
| | 7 days | 0.3 ml |
| | 14 days | 0.4 ml |
| | 21 days | 0.5 ml |
| | over 21 days | 1.0 ml/10 kg |

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

Not applicable.

**4.11 Withdrawal Period(s)**

**Cattle:**

Meat and offal: 35 days

Milk: 8 days

**Pigs:**

Meat and offal: 20 days

**Sheep:**

Meat and offal: 20 days

Milk: 8 days

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracyclines

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 receptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis. Maxoject LA is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium Formaldehyde Sulphoxylate

Magnesium Oxide Light

2-Pyrrolidone

Povidone K12

Monoethanolamine

Hydrochloric Acid

Water for Injections

**6.2 Incompatibilities**

Do not mix the product with other medicinal products.

**6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
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.

**6.5 Nature and composition of immediate packaging**

Amber type II glass vials of 50 ml, and 100 ml with Chlorobutyl bungs and aluminium seals containing a clear solution for injection.
Not all pack sizes may be marketed.

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

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

**7 MARKETING AUTHORISATION HOLDER**

Chem-Pharm Limited
Ballyvaughan
Co. Clare
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10823/007/001

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

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

**10 DATE OF REVISION OF THE TEXT**

September 2020