Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Maxoject LA 200 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance		
Oxytetracycline as Oxytetracycline Dihydrate	200.0	mg
Excipients		
Sodium Formaldehyde Sulphoxylate	2.0	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 Injection 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 or 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 Injection.
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.

Special Precautions to be taken by the Person Administering the 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.

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 Injection can be safely administered during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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

To ensure a correct dosage bodyweight should be determined as accurately as possible.

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

Not applicable.

4.11 Withdrawal period(s)

Cattle:
Milk: 8 days
Meat and offal: 35 days
Sheep:
Milk: 8 days
Meat and offal: 20 days
Pigs:
Meat and offal: 20 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01 AA06.
Pharmacotherapeutic Group: Oxytetracycline

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. 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 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary 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.
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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chem-Pharm
Ballyvaughan
Co. Clare
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10823/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1998
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

October 2021