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 mg

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium Formaldehyde Sulphoxylate	2 mg
Magnesium Oxide Light	
2-Pyrrolidone	
Povidone K12	
Monoethanolamine	
Hydrochloric Acid	
Water for Injections	

A clear amber solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, pigs and piglets.

3.2 Indications for use for each target species

Oxytetracycline is active against a wide range of Gram-positive and Gram-negative pathogenic bacteria, certain rickettsia and the larger viruses. The veterinary medicinal product 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.

3.3 Contraindications

Do not use in animals suffering from hepatic or renal damage.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not dilute this veterinary medicinal product.

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

Special precautions to be taken by the person administering the veterinary 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Cattle, sheep, pigs and piglets.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1] Hypersensitivity reaction[2] Anaphylaxis[2]

[1] Transient.
[2] Sometimes fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The use of tetracycline during the period of tooth and bone development, including late pregnancy may lead to tooth discoloration. Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Deep intramuscular use.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 35 days.
Milk: 8 days.

Pigs:
Meat and offal: 20 days.

Sheep:
Meat and offal: 20 days.
Milk: 8 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

ATCvet Code: QJ01AA06

4.2 Pharmacodynamics

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. The veterinary medicinal product is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

Do not store above 25°C.
Protect from light.

5.4 Nature and composition of immediate packaging

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.

Outer packaging and sales presentations:

- Cartons containing 1 vial.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chem-Pharm Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10823/007/001

8. DATE OF FIRST AUTHORISATION

01/10/1998

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

05/10/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).