1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procycline LA 200mg/ml solution for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

200.0 mg Oxytetracycline; equivalent to 215.68 mg oxytetracycline dihydrate.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Magnesium oxide	
Dimethylacetamide	
Sodium formaldehyde sulfoxylate	3.0 mg
Monoethanolamine	
Water for injection	

A clear, pale amber to light brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is recommended in the treatment of a wide range of common systemic, respiratory and local infections caused by, or associated with, organisms sensitive to Oxytetracycline.

3.3 Contraindications

Do not use in sheep producing milk for human consumption.
Do not administer by the intravenous route.
Do not use in horses, dogs and cats.
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:

Use of the veterinary medicinal 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 veterinary medicinal product to animals:

This veterinary medicinal product contains dimethylacetamide (DMAC) and care should be taken to prevent absorption through the skin. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep and pigs:

Undetermined frequency (cannot be estimated from the available data)	Injection site reactions[1] Allergic reactions

[1]Transient

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:
Use of tetracycline during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product should not be diluted or mixed with solutions of calcium salts.

3.9 Administration routes and dosage

For deep intramuscular use only.

The recommended dosage is 20 mg per kg or 10 ml per 100 kg bodyweight.

SPECIES	DOSE (ml) / Kg Bodyweight
Cattle	10.0 ml 100 kg
Calf	5.0 ml / 50 kg
Sheep	2.5 ml / 25 kg
Lamb	1.0 ml / 10kg
Piglet	0.5 ml / 5 kg
Weaner	2.0 ml / 20 kg
Fattener / Sow	7.5 ml / 75 kg

These are average recommendations. The maximum dose volume recommended at any one site is:

Cattle	20 ml
Sheep	5 ml
Pig	10 ml

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

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

Do not exceed the stated dose.

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: 28 days.
Milk: 8 days.

Sheep:
Meat and offal: 28 days.
Milk: Not authorised for use in sheep producing milk for human consumption.

Pigs:
Meat and offal: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01AA06

4.2 Pharmacodynamics

Oxytetracycline interferes with bacterial protein synthesis. Following diffusion through the outer cell membrane, oxytetracycline is actively transported to the inner cytoplasmic membrane. It binds to receptors on the 30 S subunit of the bacterial ribosomes and interferes with the binding to the aminoacyl-transfer RNA in the messenger RNA ribosome complex. This blocks the addition of amino acids to the elongating peptide chain and inhibits protein synthesis.
Only a small portion of the drug is irreversibly bound and it appears that the reversibly bound antibiotic is responsible for antibacterial action.

4.3 Pharmacokinetics

Absorption
Oxytetracycline is rapidly absorbed from the injection site with peak plasma levels within 2-6 hours. Therapeutic plasma levels are maintained for 48-72 hours post treatment.

Distribution

Oxytetracycline diffuses throughout the body and is found in the highest concentration in kidney, liver, spleen and lung. It is also deposited at active sites of ossification. Oxytetracycline passes through the bovine placenta and enters the foetal circulation. The concentration in the foetal blood is approximately one half that in the maternal blood. Oxtetracycline diffuses with difficulty into the cerebrospinal fluid.

Metabolism/Biotransformation
Oxytetracycline undergoes metabolism to various degrees. The most frequently identified substance in urine, faeces and tissues is the parent tetracycline. As much as 30% will be excreted unchanged in the faeces. Oxytetracycline is reversibly bound to plasma protein and widely distributed. It is removed from blood by the liver and high concentrations are achieved in parenchyma and bile. Bile concentrations may be 30 times that of blood. However, enterohepatic circulation limits bile secretion and prolongs maintenance of therapeutic concentrations.

Excretion
Oxytetracycline is primarily excreted in the parent form by the kidney. Faecal elimination also occurs regardless of the route of administration. Less than 2% of an administered dose is excreted by the milk route.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

The veterinary medicinal product should not be diluted or mixed with solutions of calcium salts.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

100 ml amber, type II glass vial closed with nitryl stopper and aluminium seal.

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

Interchem (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10555/008/001

8. DATE OF FIRST AUTHORISATION

16/11/2012

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

04/10/2024

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).