1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Procycline LA 200 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance
Oxytetracycline (as dihydrate) 200.0 mg

Excipients
Sodium formaldehyde sulfoxylate 3.0 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

Procycline LA 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.

4.3 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 animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 veterinary medicinal product to animals

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

4.6 Adverse reactions (frequency and seriousness)

Transient local reactions may occur at the injection site
Use of tetracycline during the period of tooth development, including late pregnancy, may lead to tooth discolouration.Occasional allergic reactions occur but these are rare.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Procycline LA should not be diluted or mixed with solutions of calcium salts.

4.9 Amounts to be administered and administration route

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 / 10 kg
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.

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

Do not exceed the stated dose.

4.11 Withdrawal period(s)

Milk should not be used for human consumption during treatment. Milk for human consumption may be taken after 8 days after the last treatment. Do not use in sheep producing milk for human consumption. Animals should not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption after 28 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracyclines
ATCvet code: QJ01AA06

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium oxide
Dimethylacetamide
Sodium formaldehyde sulfoxylate
Ethanolamine
Water for Injections

6.2 Major incompatibilities

This product should not be diluted or mixed with solutions of calcium salts.

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

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

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

7 MARKETING AUTHORISATION HOLDER

Interchem Ireland Ltd
29 Cookstown Industrial Estate,
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10555/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 16th November 2012
Date of last renewal: 15th November 2017

10 DATE OF REVISION OF THE TEXT

March 2018