Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanacycline LA Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Oxytetracycline (as dihydrate)	200.0 mg

Excipients:

Dimethylacetamide	0.45 mg
Sodium formaldehyde sulphoxylate	3.0 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs

4.2 Indications for use, specifying the target species

Chanacycline 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 use un animals with known hypersensitivity to the active ingredient.
Do not use in horses, dogs or cats.
Do not administer by the intravenous route.

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

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

4.6 Adverse reactions (frequency and seriousness)

Transient local reactions may occur at the injection site.

Occasional allergic reactions occur but these are rare.

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

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Chanacycline 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.
To ensure a correct dosage, body weight should be determinated as accurately as possible.

Species	Dose (ml) / Bodyweight (kg)
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
Fattner/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

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

Do not exceed the stated dose.

4.11 Withdrawal Period(s)

Cattle
Milk: 8 days
Meat and offal: 28 days

Sheep
Milk: Not to be consumed
Meat and offal: 28 days

Pigs
Meat and offal: 28 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, oxytetracycline.
ATCvet code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic with a broad range of antibacterial activity.
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 properties

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

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 sulphoxylate
Monoethanolamine
Water for Injections

6.2 Incompatibilities

Chanacycline LA Injection 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 25ºC.
Do not freeze.

6.5 Nature and composition of immediate packaging

A clear amber solution in a 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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co Galway.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/023/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10 DATE OF REVISION OF THE TEXT

February 2016