**IRISH MEDICINES BOARD ACT 1995, as amended**

**European Communities (Animal Remedies) (No. 2) Regulations 2007**

VPA: **10894/002/001**
Case No: 7008119

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

**Alfa Med Limited**

**Unit 6**, **Fermoy Enterprise Park**, **Co. Cork**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Alfacycline LA Solution for Injection**

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **16/07/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alfacycline LA Solution for Injection.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active Substance**
Oxytetracycline (as dihydrate) 200 mg

**Excipients**
Sodium formaldehyde sulfoxylate 3 mg

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection.
A clear, pale amber to light brown solution.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, sheep and pigs.

### 4.2 Indications for use, specifying the target species

*Alfacycline LA Solution for Injection* is recommended in the treatment of common systemic, respiratory amd 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 in animals with known hypersensitivity to the active ingredient.
Do not administer intravenously.
Do not use in horses, dogs and cats.

### 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 oxytetracycline 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 oxytetracycline 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

*Alfacycline LA Solution for Injection* should not be diluted or mixed with solutions of calcium salts.

## 4.9 Amounts to be administered and administration route

For deep intramuscular injection 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 |
| 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 |

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 or for 8 days thereafter.
Do not use in sheep producing milk for human consumption.
Animals should not be slaughtered for human consumption during treatment or for 28 days thereafter.

# 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systematic use, tetracyclines
ATCvet code: QJ10AA06

## 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 receptors on the 30 S subunit of the bacterial ribosome complex. This blocks the addition of amino acids to the elongated peptide chainand 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 48-82 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. Oxytetracycline 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 concentration 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.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Magnesium oxide
Dimethylacetamide
Sodium formladehyde sulfoxylate
Monoethanolamine
Water for injection

## 6.2 Incompatibilities

The 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: 4 weeks.

## 6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze.

## 6.5 Nature and composition of immediate packaging

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

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

## 7 MARKETING AUTHORISATION HOLDER

AlfaMed Ltd.,
Unit 6,
Fermoy Enterprise Park
Fermoy
Co. Cork
Ireland

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10894/002/001

## 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th February 2010

## 10 DATE OF REVISION OF THE TEXT

16th July 2010