IRISH MEDICINES BOARD ACT 1995, as amended

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

VPA: **10894/001/001**
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 10% 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 10% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Oxytetracycline Hydrochloride	100.0	mg

Excipients

Sodium formaldehyde sulfoxylate	1.0	mg

For a 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

General indications

The 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.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.
Do not use in sheep producing milk for human consumption.
Do not administer intravenously.
Do not use in horses, dogs or 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

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)

The product is well tolerated but transient local reactions may occur at the infection 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 discolouration.

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

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

4.9 Amounts to be administered and administration route

For intramuscular injection only.
The recommended dosage is 5 mg per kg or 5 ml per 100 kg bodyweight.
To ensure a correct dosage, body weight should be determined as accurately as possible.

SPECIES	**DOSE (ml) / Kg Bodyweight**
Cattle	5.0 ml / 100 kg
Calf	2.5 ml / 50 kg
Sheep	1.25 ml / 25 kg
Lamb	0.5 ml / 10 kg
Piglet	0.3 ml / 5 kg
Weaner	1.0 ml / 20 kg
Fattner / Sow	3.8 ml / 75 kg

These are average recommendations. The period of treatment should extend from 3-5 days, depending on the severity of the condition being treated. The recommended maximum duration of therapy is 5 days. If the injection volume exceeds 25 ml, divide the dose and administer at two separate injection sites.

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 96 hours (that is, from the 9th milking in cows milked twice daily) 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 only after 28 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use, oxytetracycline.
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 properties

Absorption

Oxytetracycline is rapidly bound from the injection site with peak plasma levels within 2-6 hours. Therapeutic plasma levels are maintained for up to 24 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 the 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 Chloride
Monoethanolamine
Sodium Formaldehyde Sulphoxylate
Dimethylacetamide
Water for Injection

6.2 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 25ºC.
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Stored in 100 ml amber, type II glass vial, closed with a grey 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 national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10894/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th October 2009

10 DATE OF REVISION OF THE TEXT

16th July 2010