IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10990/011/001
Case No: 7002257

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Univet Limited

Tullyvin, **Cootehill**, **Co. Cavan.**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Duocycline 5% Solution for Injection

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duocycline 5% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substance	
Oxytetracycline hydrochloride	50 mg
Excipients	
Sodium formaldehyde sulfoxylate	1.0 mg
Dimethylacetamide	0.7 ml

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

Duocycline 5 Injection 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 in animals with known hypersensitivity to the active ingredients.
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

None.

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)

Duocycline 5 Injection is well tolerated but 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 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

Duocycline 5 Injection should not be diluted or mixed with solutions of calcium salts.

4.9 Amounts to be administered and administration route

For intramuscular use only.
The recommended dosage is 5 mg oxytetracycline per kg or 10 ml per 100 kg bodyweight.

SPECIES	**DOSE (ml) / Kg Bodyweight**
Cattle	10.0 ml / 100 kg
Calf	5 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 period of treatment should extend from 3-5 days, depending on the severity of the condition being treated. The maximum recommended 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 from the last treatment (that is, at the 9th milking in cows milked twice daily).
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 from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Summary presentation of the active ingredient

Oxytetracycline is a bacteriostatic antibiotic with a broad range of antibacterial activity. Oxytetracycline is rapidly absorbed from the injection site with peak plasma levels within 2-6 hours. Therapeutic plasma levels are maintained for up to 24 hours post treatment.

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.

5.2 Pharmacokinetic properties

Only a small portion of the drug is irreversibly bound and it appears that the reversibly bound antibiotic is responsible for antibacterial action.

Absorption

Oxytetracycline is rapidly absorbed 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 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 in the milk.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Chloride
Sodium formaldehyde sulfoxylate
Monoethanolamine
Dimethylacetamide
Water for Injections

6.2 Incompatibilities

Duocycline 5 Injection should not be diluted or mixed with solutions of calcium salts.

6.3 Shelf-life

The shelf life is two years from the date of manufacture.
Once a vial is broached, use the contents within four weeks

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

A clear amber solution in a 100 ml Type II amber 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

Univet Ltd.,
Tullyvin,
Cootehill,
Co. Cavan.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/11/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003