IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10823/006/001**
Case No: 7007114

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:

Chem-Pharm

Ballyvaughan, **Co. Clare**, **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:

Maxoject 10% w/v Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Maxoject 10% w/v Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Oxytetracycline Hydrochloride 100.0 mg

Excipients
Sodium Formaldehyde Sulfoxylate 1.5 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, Pigs.

4.2 Indications for use, specifying the target species

Maxoject 10 Injection is indicated in the treatment of a wide range of common systemic, respiratory and local infections caused by or associated with organisms sensitive to Oxytetracycline in cattle, sheep and pigs.

4.3 Contraindications

Contraindicated in animals suffering from renal or hepatic damage and in animals with known hypersensitivity to oxytetracycline.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

If the volume of product to be administered is greater than 20 ml it should be divided and injected into two sites.

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 Product to Animals
None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The use of tetracycline during the period of tooth development, including late pregnancy may lead to tooth discoloration. Maxoject 10 Injection can be safely administered during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by intramuscular or slow intravenous injection in cattle and by intramuscular injection in pigs and sheep. The recommended dosage is as follows:-

Cattle: 4 mg/kg (2ml per 50kg bodyweight) daily for three to five days.
Sheep: 4 - 9 mg/kg (2 - 4.5 ml per 50kg bodyweight) daily for three to five days.
Pigs: 4 - 9 mg/kg (2 - 4.5 ml per 50 kg bodyweight) daily for three to five days.

It is recommended that when the intravenous route is used in cattle, no more than two consecutive daily injections are administered.

To ensure a correct dosage bodyweight should be determined as accurately as possible.

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

Not applicable.

4.11 Withdrawal Period(s)

Cattle:
Milk: 84 hours
Meat and offal: 18 days

Sheep and pigs:
Meat and offal: 15 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Oxytetracycline
ATC Vet Code: QJ01 AA06.

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the amino-acyl transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium chloride
Dimethylacetamide
Ethanolamine
Citric acid
Sodium formaldehyde sulfoxylate
Water for injections

6.2 Incompatibilities

Dilution with solutions of calcium salts will cause precipitation and must be avoided.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25^{o}C.
Protect from light.

6.5 Nature and composition of immediate packaging

100 ml amber Type II glass vials with nitryl rubber bungs and aluminium seals.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chem Pharm Ltd.
Ballyvaughan
Co. Clare

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/006/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008