IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10980/001/001**
Case No: 7004423

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:

Alfasan International B.V.

Kuipersweg 9, **3449 JA Woerden**, **Woerden 3440ab**, **Netherlands**

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:

Oxytetracycline Injection 10%

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

Oxytetracycline Injection 10%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Oxytetracycline Hydrochloride 100.0 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

4.2 Indications for use, specifying the target species

For the treatment of pneumonia and shipping fever complex caused by organisms sensitive to oxytetracycline including *Pasteurella* spp., *Haemophilus* spp., *Streptococcus* spp., *Corynebacteriae* and *Staphylococcus* spp.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

Do not administer by other than the intramuscular route.

4.4 Special warnings for each target species

None known.

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 Medicinal Product to Animals

Avoid the introduction of contamination during use.

4.6 Adverse reactions (frequency and seriousness)

Mild irritation (oedematous swelling) at the injection site following intramuscular administration is observed in cows.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

The use of tetracyclines 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

Do not dilute or mix with other compounds.

4.9 Amounts to be administered and administration route

For intramuscular administration only.

Dosage:

Cattle: 5-10 mg/kg bodyweight daily for 3 days.
Calves: 10 mg/kg bodyweight daily for 3 days.

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

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

None known.

4.11 Withdrawal Period(s)

Meat: 21 days
Milk: 3 days (at the sixth milking in cows milked twice daily).

Animals intended for human consumption must not be slaughtered during treatment.

Milk from treated animals may not be taken for human consumption during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01 AA06
Pharmacotherapeutic Group: Antibacterials for systemic use, oxytetracycline

Broad spectrum antibiotic with bacteriostatic action against Gram-positive and Gram-negative germs such as *E. coli*, *Pasteurella*, *Salmonella*, *Brucella*, *Streptococcus*, *Clostridium*, *Haemophilus*, *Corynebacterium*, *Anthrax*, *Staphylococcus*. *Rickettsia*, *Mycoplasma*, spirochaetes, and *Actinomyces*. After parenteral administration oxytetracycline 10 % is distributed very quickly in blood and tissues.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Chloride
Polyvinylpyrrolidone
Sodium Formaldehyde Sulphoxylate
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Glycerol Formaldehyde
Monoethanolamine
Water for Injection

6.2 Incompatibilities

In the absence of compatability studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life following first broaching of the immediate packaging: 28 days

6.4 Special precautions for storage

Store in a refrigerator (2^{o}C-8^{o}C). Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Amber type II glass vial, sealed with a butyl rubber stopper and non reusable aluminium closures.

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

Alfasan International B.V.,
Kuipersweg 9 – 3449 JA Woerden,
P.O. Box 78 – 3440 AB Woerden,
Holland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10980/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT