IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10980/005/001**
Case No: 7005143

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:

Tylosin 20% 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

Tylosin 20 % Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance	
Tylosin	200 mg
(as Tylosin Tartrate)	
Excipient	
Benzyl Alcohol	40 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 and pigs.

4.2 Indications for use, specifying the target species

Cattle:
Respiratory tract infections caused by *Mycoplasma* spp..
Metritis caused by *Corynebacterium pyogenes*.
Mastitis caused by *Streptococcus* spp. and *Staphylococcus* spp..

Pigs:
Arthritis caused by *Mycoplasma hyosynoviae* and *Staphylococcus* spp..
Pneumonia caused by *Mycoplasm*a spp. and *Corynebacterium pyogenes*.
Erysipylas caused by *Erysipelothrix rhusiopathiae*.
Dysentery associated with *Treponema hyodysenteria*.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

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 Product to Animals

Contact dermatitis due to tylosin is reported in literature. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Pigs have been reported to react to injection by developing oedema, pruritis, oedema of rectal mucosa and mild anal protrusion.
Local tissue reaction can occur at the injection site.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Antagonism with penicillins and cefalosporins.

4.9 Amounts to be administered and administration route

By intramuscular injection:

Pigs: 10 mg per kg bodyweight daily for 3 days.
Cows, calves: 10 mg per kg bodyweight daily for 3 – 5 days.

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

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

Pigs have been reported to react to injection by developing oedema, pruritis, oedema of rectal mucosa and mild anal protrusion.

4.11 Withdrawal Period(s)

Cattle
Meat: 35 days
Milk: 96 hours (at the eighth milking in cows milked twice daily).

Pigs
Meat: 21 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01FA90
Pharmacotherapeutic Group: Macrolides, tylosin

5.1 Pharmacodynamic properties

Tylosin is a macrolide antibiotic active mainly against Gram-positive bacteria, but it is also active against *Mycoplasma*, *Erysipelothrix*, Spirochaetes, *Corynebacterium* and certain Gram-negative bacteria.

5.2 Pharmacokinetic properties

Following intramuscular administration in pigs and cattle peak plasma concentrations were reached after 1 - 2 hours. Tylosin is well distributed to organs and tissues. Following intramuscular administration the elimination half-life was 2-3 hours in cattle but in pigs could exceed 24 hours. In milk and lung tissue tylosin concentrations exceeded those in plasma. Binding is approximately 40%. Tylosin is excreted mainly through the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite
Disodium Edetate
Sodium Citrate
Benzyl Alcohol
Propylene Glycol
Water for Injections

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 ($2^{o}C – 8^{o}C$). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

A limpid, yellow coloured, injectable solution packed in 100 ml amber vials, sliconized glass type II, with butyl rubber stoppers and non reusable aluminium closures.

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

Absorb spills with an inert material.

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 10980/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT