IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10980/004/001**
Case No: 7005142

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:

Dihydrostreptomycin 25% 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

Dihydrostreptomycin 25% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Dihydrostreptomycin (as sulphate) 250.0 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

Indicated for the treatment of infections caused by or associated with dihydrostreptomyin susceptible organisms.

4.3 Contraindications

Do not use in animals with impairment of kidney function or obstruction of urine flow.
Do not use in animals with known hypersensitivity to the active substance.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No specific effects on reproductive performance.

4.8 Interaction with other medicinal products and other forms of interaction

Enhanced nephrotoxicity may become evident with concurrent administration of aminoglycosides and other potentially nephrotoxic agents.

4.9 Amounts to be administered and administration route

By single intramuscular injection:

10-20 mg dihydrostreptomycin per kg bodyweight.

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

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

Prolonged administration may cause renal damage or may affect balance or hearing. These effects may be permanent.

4.11 Withdrawal Period(s)

Meat: 30 days
Milk: 60 hours (from 5th milking when cows are milked twice daily).

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01GA90
Pharmacotherapeutic Group: Antibacterials for systemic use, dihydrostreptomycin

5.1 Pharmacodynamic properties

Dihydrostreptomycin is an aminoglycoside antibiotic.
Dihydrostreptomycin is considered to be a narrow spectrum antibiotic.
It is active against Gram-negative bacteria and *Leptospira* spp.
The antibiotic is absorbed rapidly after intramuscular injection and also is rapidly distributed.

5.2 Pharmacokinetic properties

In cattle DNS serum peaks were obtained at 1 to 2 hours after i.m. injection. Clearance from the blood was at an exponential rate. Excretion was at an exponential rate however small amounts were detected in the urine at 96 hours after administration. Most of the administered dose of DHS was eliminated in 12 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite
Disodium Edetate
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Citrate
Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must 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 below 25^0C. Protect from light.

6.5 Nature and composition of immediate packaging

A limpid, slightly yellow coloured, solution for injection packed in 100 ml vials, amber 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

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
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10980/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th Septemebr 2008

10 DATE OF REVISION OF THE TEXT