IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10980/009/001**
Case No: 7005141

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:

Pen-Strep 20/20 Suspension 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 **30/09/2007**.

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

Pen-Strep 20/20 Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:		
Procaine Benzylpenicillin	200.0	mg
Streptomycin Sulfate	200.0	mg
Procaine Hydrochloride	20.0	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Infections caused by or associated with penicillin and streptomycin susceptible organisms.

4.3 Contraindications

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

Do not administer by the intravenous route.

4.4 Special warnings for each target species

Hypersensitivity reactions to the active ingredients may occur in treated animals.

4.5 Special precautions for use

Special precautions for use

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

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances can occasionally be serious.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention

4.6 Adverse reactions (frequency and seriousness)

None known.

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

None known.

4.9 Amounts to be administered and administration route

For intramuscular administration:
1 ml per 20kg body weight 1 or 2 times 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)

Cattle:
Meat: 70 days
Milk: 5 days (from 11th milking when cows are milked twice daily).

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01RA01
Pharmacotherapeutic Group: Penicillins, combinations with other antibacterials.

5.1 Pharmacodynamic properties

Pen-Strep 20/20 injectable suspension is an effective antimicrobial preparation containing procaine penicillin and streptomycin sulfate.
Procaine penicillin is a narrow spectrum antibiotic, with bactericidal activity against Gram-positive bacteria.
Streptomycin shows a bactericidal action against Gram-negative bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Citrate
Polyvidone/Povidone
Sodium Formaldehyde Sulfoxylate
Glycerol formal
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Disodium Edetate
Methylhydroxyethylcellulose
Polysorbate 80
Water for injection

6.2 Incompatibilities

In the absense of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicianl 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

Do not store above 25°C. Protect from light.
Do not store in a refrigerator and do not freeze.

6.5 Nature and composition of immediate packaging

A white to off-white aqueous suspension supplied in type II amber glass vials with butylrubber 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,
Holland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10980/009/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT