IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10823/003/001**
Case No: 7001400

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) 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:

Interkan Intrammary Suspension

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.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

(NOTE: 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

Interkan intramammary suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose syringe contains:

Active substances		
Procaine Benzylpenicillin		100.0 mg
Kanamycin		37.3 mg
Excipients		
Base	to	5.0 g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.
A sterile off-white oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating cows.

4.2 Indications for use, specifying the target species

For the treatment of acute and subacute bovine mastitis caused by bacteria sensitive to penicillin and kanamycin therapy including the following:

Corynebacterium pyogenes
Staphylococcus aureus
Escherichia coli
Streptococcus agalactiae
Streptococcus dysgalactiae
Streptococcus uberis

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.

4.4 Special warnings for each target species

None known

4.5 Special precautions for use

Special precautions for use in animals

Aseptic precautions should be observed at all times.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Allergic reaction to these substances may 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 or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Interkan may be used in pregnant animals. Interkan is indicated for use in lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Intramammary use.

The contents of one syringe should be infused into each quarter via the teat canal immediately after milking once daily for three consecutive days.

Before infusion, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injection nozzle. Following infusion, it is advisable to use a teat dip or spray.

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

Not applicable.

4.11 Withdrawal Period(s)

Foodstuffs must not be taken for human consumption during the treatment period.

Edible Tissues: 7 days
Milk: 96 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Penicillins are bactericidal by interfering with cell wall synthesis. Benzylpenicillin is particularly active against gram-positive bacteria. Procaine benzylpenicillin is slightly soluble.

Kanamycin is one of the aminoglycosides, which are bactericidal by inhibiting protein synthesis within the cell. They are taken up into bacteria by an oxygen-dependent process and are therefore inactive against anaerobic bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin

Soft White Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.
For single use only.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

7 ml polyethylene pre-filled click lock self venting syringe containing 5 g of suspension.

Pack sizes: 24 syringes.

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

Any unused product or waste material 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 10823/3/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th June 2005

10 DATE OF REVISION OF THE TEXT

12th October 2006