

**IRISH MEDICINES BOARD ACT 1995**

**ANIMAL REMEDIES REGULATIONS, 2005**

**(S.I. No. 734 of 2005)**

VPA: **10277/017/001**

Case No: 7002016

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:

**Schering Plough Limited**

**Shire Park,, Welwyn Garden City,, Hertfordshire AL7 1TW, United Kingdom**

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:

**Cepramycin Milking Cow**

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

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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

Cepramycin Milking Cow.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 9g dose contains anhydrous Cefalexin 500 mg and dihydrostreptomycin (as dihydrostreptomycin sulphate) 500 mg.

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Intramammary infusion, lactating cow.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Lactating Cows.

##### 4.2 Indications for use, specifying the target species

For the treatment of mastitis caused by organisms susceptible to the combination of cephalixin and dihydrostreptomycin in lactating cows.

##### 4.3 Contraindications

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

##### 4.4 Special warnings for each target species

None.

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

None.

### **Special Precautions to be taken by the Person Administering the Product to Animals**

Operators should avoid contact with this preparation as occasionally skin allergy may occur.

Penicillins and cephalosporins may cause hypersensitivity following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know that you are sensitized, or if you have been advised not to work with such preparations.

Handle this product with care to avoid exposure.

If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to your doctor. Swelling of the face, lips or eyes, or difficulty 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 cattle. The product is intended 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**

The contents of one injector should be infused into each affected quarter, via the teat canal, immediately after milking and at twelve hourly intervals for a total of up to 3 infusions. Before the infusion is made, the teat should be thoroughly cleaned and disinfected. Care should be taken to avoid contamination of the injector nozzle after the cap has been removed.

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

Not applicable.

## **4.11 Withdrawal Period(s)**

Milk for human consumption must not be taken from cows during treatment. With cows milks twice daily, milk for human consumption may only be taken from 96 hours after the last treatment.

Animals should not be slaughtered for human consumption during treatment. Cows may be slaughtered for human consumption only after 7 days from the last treatment.

## **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Cefalexin is a broad spectrum penicillinase-resistant beta-lactam antibiotic. It exerts bactericidal action by inhibiting cell wall synthesis.

Dihydrostreptomycin is an aminoglycoside antibiotic. The drug binds to the receptors of the 30S subunit of the ribosome where it induces misreading of the genetic code and consequently causes fatal inhibition of ribosomal protein synthesis in the bacteria.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sorbitan sesquioleate  
Hydrogenated soya oil  
Arachis oil

### **6.2 Incompatibilities**

None described.

### **6.3 Shelf-life**

The shelf-life expiry date for this product shall not exceed 2 years from the date of its manufacture.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and composition of immediate packaging**

Each 10 ml white polyethylene syringe contains a sterile Intramammary injection (9 g). Sold in boxes of 20 syringes.

### **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**

Schering-Plough Limited  
Schering-Plough House  
Shire Park  
Welwyn Garden City  
Hertfordshire AL7 1TW  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10277/17/1

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

13<sup>th</sup> December 2001