IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10126/032/001**
Case No: 7006370

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:

Bimeda Chemicals

Broomhill Road, **Tallaght**, **Dublin 24.**, **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:

Kefamast Dry Cow Intramammary 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.

The authorisation,unless revoked, shall continue in force from **06/08/2009**.

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

KEFAMAST Dry Cow Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:	
Active Substances	
Anhydrous Cefalexin (as Cefalexin)	500 mg
Dihydrostreptomycin (as Dihydrostreptomycin Sulphate)	500 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Dry Cows

4.2 Indications for use, specifying the target species

For the treatment of sub clinical mastitis infection present at drying off and to assist in preventing new infections occurring during the dry period.

4.3 Contraindications

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

Do not use in lactating cows.

Do not use within 40 days of the estimated calving date.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Not intended for use within 40 days of the estimated calving date.

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

Operators should avoid contact with this preparation as occasional 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 sensitised, 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 skin rash following exposure, seek medical advice and show this warning to your doctor. Swelling of the face, lips or 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

This product may be used in pregnant cattle. This product is contra-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

For intramammary use only.

The contents of one injector should be infused into the teat canal of each quarter immediately after the last milking of the lactation.

Before infusion, the teat should be thoroughly cleaned and disinfected. Care should be taken to avoid contamination of the injector nozzle after the protective cap has been removed.

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

Not applicable.

4.11 Withdrawal Period(s)

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

With cows milked twice daily, milk for human consumption may only be taken from 60 hours after calving (that is, from the fifth milking).

If calving occurs within 40 days of treatment, milk for human consumption may only be taken from 40 days plus 60 hours after treatment.

Animals for human consumption may only be slaughtered from 28 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Cefalexin; combinations with other antibacterials.

ATCvet Code: QJ51RD01

5.1 Pharmacodynamic properties

Cefalexin is a broad spectrum, penicillinase-resistant beta-lactam antibiotic. It exerts bactericidal action by inhibiting cell wall synthesis. It has a half-life of about 1 hour and is excreted through the kidneys in the urine.

Dihydrostreptomycin is an aminoglycoside antibiotic. The drug binds to receptors on 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. The half-life of dihydrostreptomycin is 1-2 hours. It is eliminated entirely by glomerular filtration.

Aminoglycosides have a synergistic effect with beta-lactam antibiotics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cera alba
Liquid Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A sterile intramammary injection provided in 10 ml white low density polyethylene syringe for single use only. Packaged in buckets of 120 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

Bimeda Chemicals Limited
Broomhill Road
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/032/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

6th August 2009