IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10126/002/001**
Case No: 7006919

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:

Cloxamast 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 **16/11/2009**.

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

Cloxamast Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5g dose contains:

Active substances

Ampicillin (as Ampicillin Sodium)	75 mg
Cloxacillin (as Cloxacillin Sodium)	200 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.

A cream to off-white oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating Cow.

4.2 Indications for use, specifying the target species

For the treatment of clinical mastitis in lactating cows caused by:

Streptococcus agalactiae
Streptococcus dysgalactiae
other streptococcal species
Staphylococci (penicillin resistant and sensitive strains)
Corynebacterium pyogenes
Escherichia coli

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active ingredients

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.

Users should avoid contact with this preparation as occasional skin allergy may occur.

Hypersensitivity to penicillins may lead to cross reactions to celphalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this product with care to avoid exposure, taking all the recommended precautions.

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 require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Not applicable.

4.7 Use during pregnancy, lactation or lay

Cloxamast 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

The contents of one syringe should be infused into each affected quarter via the teat canal, immediately after milking at 12 hour intervals for three consecutive milkings. Before infusion is made, the teat should be thoroughly cleaned and disinfected. Care should be taken to avoid contamination of the injector nozzle. Following infusion, it is advisable to use a teat dip or spray.

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

Overdosing may invalidate the stated withdrawal times.

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animal: 7 days.

Milk: With cows milked twice daily, milk for human consumption may only be taken from 72 hours (i.e. sixth milking) from last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials, combination of penicillins for intramammary use
ATCvet Code: QJ51CR50

5.1 Pharmacodynamic properties

Cloxamast is an intramammary product for the routine treatment of mastitis in lactating cows.

The active ingredients, ampicillin and cloxacillin are semi-synthetic penicillins, derived from the penicillin nucleus 6-amino penicillinic acid.

Ampicillin is a broad spectrum penicillin effective against many gram negative and gram positive organisms. Cloxacillin is a ß-lactamase (penicillinase) stable penicillin. It is therefore effective against both penicillin-resistant and penicillin-sensitive staphylococci.

The antibiotic combination of ampicillin and cloxacillin is broad-spectrum and active against gram-positive and gram-negative bacteria including penicillin sensitive staphylococci, Cornybacterium pyogenes and Escherichia coli.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Yellow soft paraffin
Sorbitan oleate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

4.5 g single dose polyethylene syringe.

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 Ltd.
Broomhill Road
Tallaght
Dublin 24

Trading as “Bimeda”

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

16th November 2009