

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10960/053/001**

Case No: 7005763

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:

Cross Vetpharm Group Ltd.

Broomhill Road, 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:

Bovimast DC, 500 mg cloxacillin/syringe, 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 previously revoked, shall continue in force from **08/07/2009**.

Signed on behalf of the Irish Medicines Board

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

Bovimast DC, 500 mg cloxacillin/syringe, Intramammary suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g syringe contains:

Active substance:

Cloxacillin (as Cloxacillin Benzathine)	500 mg
---	--------

Excipients:

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows

4.2 Indications for use, specifying the target species

For routine use in cows at drying off, to treat existing intramammary infections and to assist in preventing new infections occurring during the dry period. Bovimast DC contains cloxacillin which is active against the following major pathogens associated with mastitis: Penicillin resistant and sensitive *Staphylococci* spp., *Micrococci*, *Streptococcus agalactiae* and *Corynebacterium* spp.

4.3 Contraindications

Do not use in lactating cows.

Do not use within 28 days of calving.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 veterinary 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

Bovimast DC is contraindicated 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 administration. The contents of one syringe should be infused into each quarter via the teat canal immediately after the final milking of a lactation. Before infusion, the teats should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle.

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

No specific signs.

4.11 Withdrawal Period(s)

Animals intended for human consumption should not be slaughtered until 28 days after the last treatment. Milk for human consumption may only be taken from 120 hours after calving in cows with a dry period of more than 28 days. Milk for human consumption may only be taken from 28 days plus 120 hours after the last treatment in cows with a dry period of 28 days or less.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, beta-lactamase resistant penicillins
ATCvet Code: QJ51CF

5.1 Pharmacodynamic properties

Cloxacillin, a semi-synthetic penicillin resistant to Staphylococcal penicillinase, is used for dry cow intramammary infusions. Cloxacillin has a bactericidal action on a wide range of organisms implicated in chronic mastitis. The less soluble benzathine salt of Cloxacillin in a base containing 3% aluminium monostearate in mineral oil has longer persistence in the udder than the more soluble sodium salt.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Monostearate
Liquid Paraffin

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

Low density polyethylene syringe containing 3 g suspension. Each pack contains 120 syringes.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Cross Vetpharm Group Limited
Broomhill Road
Tallaght
Dublin 24,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/053/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th July 2009

10 DATE OF REVISION OF THE TEXT