## 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:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Aluminium di-tri stearate | \ |
| Liquid Paraffin | \ |

A smooth white to off-white oily suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cows.

### 3.2 Indications for use for each 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. The veterinary medicinal product contains cloxacillin which is active against the following major pathogens associated with mastitis: Penicillin resistant and sensitive *Staphylococcus* spp., *Micrococcus* spp., *Streptococcus agalactiae* and *Corynebacterium* spp.

### 3.3 Contraindications

None.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of 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:

Penicillins, 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 reactions to these substances can occasionally be serious.
People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product.
Handle this product with great care to avoid exposure, taking all 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

### 3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Lactation:
Do not use in lactating cows.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

For intramammary use. 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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No specific signs.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Meat and offal: 22 days.
Milk: 72 hours after calving if the dry period is longer than 42 days.
45 days after the last treatment if the dry period is less than or equal to 42 days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:

QJ51CF

### 4.2 Pharmacodynamics

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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Not applicable.

### 5.2 Shelf life

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

### 5.3 Special precautions for storage

Do not store above 25 °C.

### 5.4 Nature and composition of immediate packaging

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

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/003/001

## 8. DATE OF FIRST AUTHORISATION

08/07/2004

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

01/07/2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).