

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CEEMAST Dry Cow Intramammary Suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:

### Active Substances

Cefalexin	500	mg
Dihydrostreptomycin (as Dihydrostreptomycin Sulphate)	500	mg

For a full list of excipients see section 6.1

## 3 PHARMACEUTICAL FORM

Intramammary suspension.

10 ml intramammary syringe containing 9 g of a smooth pale pink or pale yellow sterile product.

## 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 in cows 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 precautions 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 a 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 interactions**

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.

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. Aminoglycosides have a synergistic effect with beta-lactam antibiotics.

## **5.2 Pharmacokinetic particulars**

Cefalexin has a half-life of about 1 hour and is excreted through the kidneys in the urine. The half-life of dihydrostreptomycin is 1-2 hours. It is eliminated entirely by glomerular filtration.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Cera alba  
Liquid paraffin

### **6.2 Major incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.

### **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 syringes for single use only. Packaged quantities of 24 and 120 syringes. Not all pack sizes may be marketed.

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

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 Animal Health Limited  
2, 3 & 4 Airton Close  
Airton Road  
Tallaght  
Dublin 24  
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## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA22033/004/001

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

Date of first authorisation: 15 February 2008  
Date of last renewal: 11 January 2013

**10 DATE OF REVISION OF THE TEXT**

May 2019