

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactatrim MC Lactating Cow Intramammary Suspension.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### Each 8 g syringe contains:

#### Active substances

Trimethoprim 40 mg

Sulphadiazine 200 mg

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Intramammary suspension.

A white to off-white suspension.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle (Lactating)

### 4.2 Indications for use, specifying the target species

The veterinary medicinal product is an intramammary suspension for the broad spectrum treatment of clinical mastitis in lactating cattle caused by organisms sensitive to the Trimethoprim/Sulphadiazine combination.

Clinically, the veterinary medicinal product has been shown to be effective in the routine treatment of mastitis in lactating cows. The veterinary medicinal product exerts a bactericidal activity at concentrations attained in the udder.

*In vitro* the veterinary medicinal product is effective against gram-positive and gram-negative bacteria including *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis* and other streptococcal species, staphylococcal spp., *Corynebacterium pyogenes*, *Escherichia coli*, and other gram-negative bacteria.

### 4.3 Contraindications

Do not use in cattle with known sulphonamide sensitivity, with hepatic damage or with blood dyscrasias.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

#### Special precautions for use in animals

Only for lactating cows, do not administer in dry periods.

Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing. Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used. Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the active substances.

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

Wash hands immediately after use.

In the event of spillage onto skin, wash the affected area immediately.

If you are known to be sensitised to sulphonamides, avoid contact with the veterinary medicinal product.

**4.6 Adverse reactions (frequency and seriousness)**

In rare cases hypersensitivity reaction may occur.

**4.7 Use during pregnancy, lactation or lay**

The veterinary medicinal product is safe for use during pregnancy and lactation.

**4.8 Interaction with other medicinal products and other forms of interactions**

No data available.

**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.

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

Not applicable

**4.11 Withdrawal period(s)**

Milk: 48 hours.

Meat & Offal: 5 days.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Antibacterial for intramammary use.

**ATCvet Code:** QJ51E

**5.1 Pharmacodynamic properties**

The veterinary medicinal product contains trimethoprim and sulphadiazine as the active ingredients which act with a unique "double blockade" mode of action. Each component disrupts a different vital link in the metabolic chain used by susceptible bacteria to make nucleic acids and proteins.

Sulphadiazine inhibits the incorporation of p-amino benzoic (PABA) acid in dihydrofolic acid. Sulphadiazine specifically competes with PABA for the enzyme dihydropteroate synthetase.

Trimethoprim selectively inhibits the enzyme dihydrofolate reductase thereby preventing the conversion of dihydrofolic into tetrahydrofolic acid, this sequential enzymatic blockage resulting in a synergistic effect and enhanced activity at the site of infection when the two compounds are present.

Thus *in vitro* trimethoprim potentiates the antimicrobial activity of sulphonamides.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Hydrogenated Castor Oil  
Arachis Oil

### **6.2 Major incompatibilities**

Not applicable

### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years  
The syringe may only be used once.  
Part used syringes must be discarded.

### **6.4 Special precautions for storage**

Store below 25°C.

### **6.5 Nature and composition of immediate packaging**

Intramammary polyethylene syringe, polyethylene plunger, polyethylene cap. The veterinary medicinal product is supplied in cartons of 24 (8 g) syringe and plastic boxes of 120 (8 g) syringes.

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

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

## **7 MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA22664/042/001

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

Date of first authorisation: 18 October 1996  
Date of last renewal: 22 October 2008

## **10 DATE OF REVISION OF THE TEXT**

February 2019