

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Boviseal Plus

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Boviseal Plus 1: Intramammary Suspension

<u>Active substance</u>	<u>mg per 3.6 g unit dose</u>
Cloxacillin (as Cloxacillin benzathine)	600

Boviseal Plus 2: Intramammary Ointment

<u>Active Substances</u>	<u>per 4 g unit dose</u>
Bismuth subnitrate	2.6 g

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Boviseal Plus 1: Intramammary suspension.  
White to off-white suspension

Boviseal Plus 2: Intramammary ointment.  
Greyish-white ointment

## 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 infection of the udder caused by organisms sensitive to Cloxacillin and to assist in preventing further infection during the dry cow period. This results in a reduction in the incidence of subclinical mastitis in cows at calving and of clinical mastitis in the dry period and the subsequent lactation (for at least 60 day after calving).

### 4.3 Contraindications

Do not use in the lactating cow.

Do not use within 28 days of the expected calving date.

Do not use within 3 days of the administration of any other intramammary preparations.

Do not use in known cases of hypersensitivity to the active ingredients.

### 4.4 Special warnings for each target species

Not applicable.

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

Care should be taken to avoid the contamination of the injector nozzle when the cap has been removed.

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 medicinal product to animals**

Penicillins and cephalosporins may cause hypersensitivity (allergy) 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 you are sensitised, or if you have been advised not to work with such preparations.

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 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**

Not for use in the lactating cow.

## **4.8 Interaction with other medicinal products and other forms of interaction**

Do not use in conjunction with any other dry cow treatment.

## **4.9 Amounts to be administered and administration route**

The contents of one syringe of Boviseal Plus I (Cloxacillin benzathine 600mg ) should be injected into each quarter immediately after the last milking prior to drying off and then massage the udder. A tube of Boviseal Plus 2 (bismuth subnitrate) is then infused into each quarter to produce a seal. Do not massage the udder or teat after infusion of Boviseal Plus 2.

Before infusion, the teat should be thoroughly cleaned and disinfected and 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**

Not applicable.

#### 4.11 Withdrawal Period(s)

Meat and offal: 28 days

Milk: 96 hours after calving

If calving occurs before 28 days after treatment, milk for human consumption may only be taken after 28 days plus 96 hours after treatment.

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use; Beta-lactamase resistant penicillins; Cloxacillin

ATCvet Code: QJ51CF02.

#### 5.1 Pharmacodynamic properties

Cloxacillin benzathine has a bacteriostatic effect at low concentrations and is bactericidal at higher concentrations. Its primary activity is against gram-positive organisms such as Staphylococci, Streptococci and *Actinomyces pyogenes*.

#### 5.2 Pharmacokinetic properties

Infusion of Boviseal Plus 2 into each udder quarter produces a seal in the teat that provides an immediate and long lasting physical barrier to entry of bacteria and other mastitis causing organisms. By preventing new intramammary infections during the dry period Boviseal Plus 2 thereby also reduces the incidence of clinical mastitis in the next lactation.

Following infusion Cloxacillin diffuses rapidly through the udder parenchyma and levels in the blood plasma increase to a peak between 2 and 8 hours. The MIC for 100% of Staphylococci, 71% of *Streptococcus agalactiae*, 100% of *Strep. dysgalactiae*, 20% of *Strep. uberis* and 93% of *A. pyogenes* is maintained in milk for more than 32 hours.

Bismuth subnitrate (Boviseal Plus 2) is not absorbed from the mammary gland,

but resides as a seal in the teat until physically removed. (Shown in cows with a dry period up to 100 days).

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Povidone

Sodium Citrate

Polysorbate 80

Disodium Edetate

Water for Injections

Liquid Paraffin

Aluminium Di Tri-Stearate

Colloidal Anhydrous Silica

#### 6.2 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**

Store below 25°C.

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

Twin single dose intramammary syringes, the first containing 3.6 g of a sterile suspension (“Boviseal Plus I”) and the second (“Boviseal Plus 2”) containing 4.0g of a sterile ointment. The syringes are composed of low density polyethylene and are sealed with a smooth, tapered hermetically sealed nozzle.

#### **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 national requirements.

### **7 MARKETING AUTHORISATION HOLDER**

Cross Vetpharm Group Ltd  
Broomhill Road  
Tallaght  
Dublin 24.

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

VPA: 10960/054/001

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

18<sup>th</sup> November 2009

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

26th October 2010