



#### **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.

##### **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 Teat Seal 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 Teat Seal II (bismuth subnitrate) is then infused into each quarter to produce a seal. Do not massage the udder or teat after infusion of Teat Seal 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)

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

Meat: 28 days

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, Beta-lactamase resistant penicillins  
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*.

Infusion of Teat Seal 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 Teat Seal 2 thereby also reduces the incidence of clinical mastitis in the next lactation.

#### 5.2 Pharmacokinetic properties

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 (Teat Seal 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

##### Teat Seal 1:

Povidone  
Sodium Citrate  
Polysorbate 80  
Disodium Edetate  
Water for Injections

##### Teat Seal 2:

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**

Do not store above 25°C.

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

Twin single dose intramammary syringes, the first containing 3.6 g of intramammary suspension (“Teat Seal I”) and the second (“Teat Seal II”) containing 4.0g of intramammary 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 according to current practice for pharmaceutical waste under national waste disposal regulations.

## **7 MARKETING AUTHORISATION HOLDER**

Cross Vetpharm Group Ltd.  
Broomhill Road  
Tallaght  
Dublin 24

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

VPA 10960/034/001

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

30th July 2009

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

27th July 2010