# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Kloxerate DC Xtra

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5.4 g syringe contains:

Active Substance(s)

| | |
|---|---|
| Cloxacillin (as Cloxacillin Benzathine) | 600 mg |
| Ampicillin (as Ampicillin Trihydrate) | 300 mg |

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Intramammary suspension.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle.

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

Kloxerate DC Xtra is formulated for use in the dairy cow at the point of drying off, that is, immediately after the last milking of the lactation in order to treat existing mastitis and to provide protection against further infections during the dry period.

Kloxerate DC Xtra is a useful aid in reducing the incidence of summer mastitis in heifers and dry cows at risk.

Kloxerate DC Xtra is active against both Gram-positive and Gram-negative organisms, which are associated with mastitis, and is effective against *Streptococcus agalactiae* and other *Streptococcus* species, Penicillin resistant and sensitive Staphylococci, *Corynebacterium* species, Escherichia coli and other susceptible Gram- negative bacteria.

Cloxacillin benzathine and ampicillin trihydrate in a long-acting base maintain effective antibacterial levels in the dry cow udder for up to 10 weeks and are non-irritant to udder tissue.

### 4.3 Contraindications

Do not use on cows, which have a short dry period. Not intended for use within 49 days of calving. (Refer to 4.11 for withdrawal periods).

In cows suffering from hypocalcaemia, it may be necessary to withhold milk for a longer period until the levels of antibiotic are below the EU maximum residue limit.

Do not use in animals with known hypersensitivity to the active ingredients. Do not use in lactating cows.

## 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

**Special precautions for use in animals:**

When infusing heifers it is important that the syringe nozzle is not introduced into the teat. The recommended procedure is as follows: The animal(s)should be properly restrained. The teats are cleaned and disinfected. The teat orifice is located and the nozzle of the syringe placed against it but NOT inserted. When the syringe plunger is depressed the antibiotic passes easily through the teat into the udder.

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

Protective gloves should always be worn when infusing heifers, to avoid skin contact with the product. 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.

Sensitised individuals or those advised not to work with such preparations should not handle this product.

This product should be handled with great care to avoid exposure, taking all recommended precautions.

Should symptoms develop following exposure such as skin rash, medical advice should be sought. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

## 4.6 Adverse reactions (frequency and seriousness)

None known.

## 4.7 Use during pregnancy, lactation or lay

Kloxerate DC Xtra is safe for use during pregnancy.

Kloxerate DC Xtra must not be used in the treatment of lactating cows.

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

None known.

## 4.9 Amounts to be administered and administration route

For intramammary infusion in dairy cows and heifers.

**Dry Off Therapy:** After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one syringe into each quarter via the teat canal.

**Summer Mastitis Therapy:** Prior to the first calving, whilst at risk to summer mastitis, clean and disinfect the teats and introduce the contents of one syringe into each quarter.

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

Not applicable.

## 4.11 Withdrawal Period(s)

Do not use on cows which have a short dry period. Not intended for use within 49 days of calving. Milk for human consumption may only be taken from 156 hours after calving.

Should a cow calve earlier than 49 days after the last treatment, milk for human consumption may only be taken from 49 days plus 156 hours after the last treatment.

Meat and offal: 28 days.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials for intramammary use, Combinations of penicillins
ATCvet Code: QJ51CR50

## 5.1 Pharmacodynamic properties

Kloxerate DC Xtra contains ampicillin and cloxacillin which are both beta-lactam antibiotics. Their structures contain the same beta-lactam ring and thiazolidine ring common to all penicillins.

Beta lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis only of growing cells. The difference in susceptibility between Gram-positive and Gram-negative bacteria depends on differences in receptor sites, on the relative amount of peptidoglycan present, on the ability of drugs to penetrate the outer cell membrane of Gram-negative bacteria and on resistance to the different types of beta-lactamase enzymes produced by the bacteria.

Ampicillin has a high activity against both Gram-positive and Gram-negative bacteria but is inactivated by beta-lactamases.

Cloxacillin is relatively resistant to staphylococcal beta-lactamases but is of lower activity than penicillin G against susceptible gram-positive bacteria and is inactive against Gram-negative bacteria.

The combination of penicillinase-resistant penicillins, such as cloxacillin, with ampicillin, against common opportunist Gram-negative bacteria, has shown synergism in many cases.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Aluminium Stearate
Liquid Paraffin

## 6.2 Incompatibilities

None known.

## 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

## 6.4 Special precautions for storage

Do not store above 25$^{o}$C.

## 6.5 Nature and composition of immediate packaging

Packs of 120 x 7 ml sterile white self-venting click lock syringes made from high-density polyethylene, each syringe containing 5.4 g of suspension.

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

# 7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

# 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/057/001

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

11$^{th}$ August 2008

# 10 DATE OF REVISION OF THE TEXT

August 2013