

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Ready to Use Chlorhexidine 0.5% w/v, Teat Dip or Spray Solution

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active Substance:

Chlorhexidine gluconate 0.5%w/v  
(added as 2.75% Chlorhexidine gluconate 20% solution)

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Excipients:

Carmosine Red (E122) 0.0003% w/v

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Other Constituents:

Glycerol 10.00% w/v  
Ethoxylated lanolin 0.5% w/v

For full list of excipients see section 6.1.

### **3. PHARMACEUTICAL FORM**

Teat Dip / Teat Spray Solution  
Description: Pink mobile liquid

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Lactating dairy cattle.

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

As an aid in the prevention of mastitis in lactating dairy cattle. After each milking the product is applied directly to the teats by spraying or by teat dipping with a teat cup.

#### **4.3 Contraindications**

None

#### **4.4 Special warnings for each target species**

For external use only. Teat dip cups should be emptied after each milking and washed thoroughly before re-use. Wash and dry udders and teats before next milking.

#### **4.5 Special precautions for use**

- i. Special precautions for use in animals  
  
None
- ii. Special precautions to be taken by the person administering the medicinal product to animals

Do not eat, drink or smoke whilst using the product.  
When the product is used as a spray, avoid working in spray mist.  
Avoid contact with eyes. In case of contact with eyes, give immediate  
prolonged irrigation with clean running water and seek medical  
attention.  
In case of ingestion, seek medical attention immediately.  
Keep away from food, drink and animal feeding stuffs.  
Wash hands after use.

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

None noted.

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

The product is a medicinal disinfectant intended as an aid against mastitis. It is designed to be used on lactating dairy cattle and is applied externally without risk to the cow.

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

Do not mix with other products.

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

The product is a ready-to-use teat dip that is applied directly to the teats of dairy cattle by either semi-automatic hand held spray equipment or by dipping using a teat cup containing the product.

Teat dipping: The product should be used directly from the container without dilution. Fill a teat cup two thirds full with the product. Dip teats of every cow immediately after milking ensuring that the full length of each teat is dipped. Refill the cup as necessary. Discard soiled teat solution. Teat dip cups should be emptied after milking and washed thoroughly before re-use. Wash and dry the udders and teats before the next milking.

Teat spraying: The product should be used directly from the container without dilution.

Spray the full length of each teat after milking. Apply immediately after each milking.

Wash and dry the udders and teats before the next milking.

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

The limited external use of this product makes an overdose very unlikely.

#### **4.11 Withdrawal period(s)**

Meat – zero days / Milk – zero hours

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Products for teats and udder, disinfectants

**ATC Vet code:** QG52A

#### **5.1 Pharmacodynamic properties**

Chlorhexidine gluconate belongs to a group of cationic materials e.g. benalkoniumchloride, cetrimide, cetylpyridinium.chloride and domiphenol bromide. Chlorhexidine is a cationic disinfectant and bactericide against many gram positive and gram negative micro-organisms. When used on cows teats and udders this product aids in the prevention of mastitis and in the prevention / healing of teat lesions. Any dryness or skin irritation, which may be caused by the activity of the bactericide, is eliminated by the addition of glycerine as an emollient.

#### **5.2 Pharmacokinetic particulars**

The product is for external use only.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Carmosine Red (E122)  
Glycerol  
Ethoxylated lanolin  
Alcohol 8 mole ethoxylate  
Isopropyl alcohol  
Water deionised

#### **6.2 Incompatibilities**

Incompatible with Iodine-based teat dips and anionic preparations such as soaps. Do not mix with other products available on the farm.

#### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale; 1 year.

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

Store upright in tightly closed original container.  
Store away from food, drink and animal feedstuffs.  
Do not store above 25°C.  
Protect from frost.  
If the contents freeze, it is important that they are thoroughly thawed and mixed before use.  
Protect from direct sunlight.  
For one milking only when transferred to the teat dip cup.  
Discard any remaining unused solutions at the end of each day.

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

Available in;  
5 litre natural or opaque high density polyethylene bottles with non-vented polyethylene/polypropylene with an expanded polyethylene cap liner.  
25, 200 & 1000\* litre blue, white or natural or opaque high density polyethylene drums closed with black or white opaque high density polyethylene screw fit caps.  
\*Ensure that all equipment and containers used for decanting not more than enough product for use that day, are fit for purpose, clean, emptied after use and washed before re-use.  
Not all pack sizes may be marketed.  
The 200 and 1000 litre containers should only be used once and should not be returned for re-filling.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. To dispose of unused product to land, you must have an authorisation under the Groundwater Regulations 2009. Harmful to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

### **7. MARKETING AUTHORISATION HOLDER**

Kilco (International) Ltd.  
Broomhouses 2 Industrial Estate  
Old Glasgow Road  
Lockerbie  
Dumfriesshire  
DG11 2SD

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

**Vm** 21357/4017

**9. DATE OF FIRST AUTHORISATION**

**Date:** 12 September 1989

**10. DATE OF REVISION OF THE TEXT**

**Date:** November 2012

**Approved:**  **29/11/2012**