

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ready to Use Summer Chlorhexidine 0.5% w/v Teat Dip or Teat Spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

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

Excipients:

Carmoisine Red (E122) 0.0003% w/v

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 Contra-indications

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

When using as a spray, avoid working in spray mist.

Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed, seek medical advice immediately and show this container or label.

Hands and exposed skin should be washed after using this product.

Do not eat, drink or smoke while using this product

Keep away from food, drink and animal feedstuffs.

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

This product contains 0.5% w/v (5000ppm) Chlorhexidine gluconate as bactericide. 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. The Diethyltoluamide is included as a fly repellent.

5.2 Pharmacokinetic particulars

The product is for external use only.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Incompatible with Iodine-based teat dips and anionic preparations such as soaps.

6.3 Shelf life

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

6.4 Special precautions for storage

Store 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 high density polyethylene bottles with opaque high density polyethylene screw-fit caps.

25, 200 & 1000* litre opaque high density polyethylene drums closed with 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 21357/4020

9. DATE OF FIRST AUTHORISATION

Date: 31 October 1994

10. DATE OF REVISION OF THE TEXT

Date: November 2012

Approved:  **29/11/2012**