

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

C-DIP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Chlorhexidine gluconate 0.5 % w/v.

Excipients:

Ponceau 4R (E124) 0.0017 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Teat Dip/Spray Solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating dairy cattle.

4.2 Indications for use, specifying the target species

For use on the teats and udders of lactating dairy cattle as an aid in the prevention of bovine mastitis.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

- a) Wash teats and udders before milking.
- b) Teat dip cups should be emptied after milking and washed before re-use.
- c) Do not mix with other products.
- d) For external use only.
- e) If signs of disease persist or appear consult your Veterinary surgeon or Veterinary practitioner.

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

- Do not eat, drink or smoke whilst using the product.
- When the product is being applied through spray equipment 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 animal feed.
- Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Skin sensitivity to chlorhexidine is rare and no suspected adverse reactions have been reported so far.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other products. This product is incompatible with soaps and other anionic materials.

4.9 Amounts to be administered and administration route

C-DIP 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

C-Dip should be used directly from the container without dilution. Fill a teat cup two thirds full with C-Dip.

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

C-DIP 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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: Zero days

Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiseptics and disinfectants, chlorhexidine.

ATCvet code: QD08AC02

5.1 Pharmacodynamic properties

Chlorhexidine gluconate belongs to a group of cationic materials e.g. benzalkonium chloride, cetrимide, cetylpyridiniumchloride and domiphenol bromide. Chlorhexidine is a cationic disinfectant and bactericide against many gram positive and gram negative micro-organisms.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol
Ethoxylated lanolin
Glycerol
Alcohol 8 mole ethoxylate
Sodium acetate trihydrate
Ponceau 4R (E124)
Deionised Water

6.2 Incompatibilities

Do not mix with 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 upright, tightly closed in the original containers.

Protect from light.

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.

6.5 Nature and composition of immediate packaging

HDPE containers containing 5, 20 or 25 litres. Not all pack sizes may be marketed.

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

As the product is harmful to fish, care should be taken to ensure that neither waste product nor used containers enter waterways, ponds, ditches etc.

Wash out container thoroughly.

For small spillages, wash away with water.

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10948/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st November 2007

10 DATE OF REVISION OF THE TEXT

August 2012