

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

K Dip, 0.5% w/v, Teat Dip / Teat Spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Chlorhexidine gluconate solution 0.5%w/v
(added as 2.5% Chlorhexidine gluconate 20% solution)

Excipients:

Ponceau 4R (E124) 0.0016 % w/v

Other Constituents:

Glycerol 5.00% w/v

Sorbitol solution 70% (non-crystallising) 5.00% w/v

Ethoxylated lanolin 1.00% 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 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.
Do not eat, drink or smoke whilst using the product
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

Teat Dipping: After milking dip the teats of each cow in the undiluted product ensuring the full length of the teat is covered.

Teat Spraying: After milking spray round the full surface of the teat including udders with the undiluted product.

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

ATCVet code: QG52A

5.1 Pharmacodynamic properties

K-Dip is a chlorhexidine based teat dip/spray which acts by killing bacteria. Additionally K-Dip contains lanolin as emollient and sorbitol and glycerol as humectants, which improve skin condition.

5.2 Pharmacokinetic particulars

The product is for external use only.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ponceau 4R (E124)
Glycerol
Sorbitol Solution 70% (non-crystallising)
Ethoxylated lanolin
Water Potable

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 composition of immediate packaging

Available in;

5 & 10 litre natural or opaque high density polyethylene bottles closed with white opaque high density polyethylene screw-fit caps.

20, 25, 200 & 1000* litre natural or opaque high density polyethylene drums closed with white opaque high density polyethylene screw fit bungs.

*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 product should be disposed of in accordance with national requirements. To dispose of unused product to land, you must have an authorisation under the Groundwater Regulations 1998. Harmful to fish and 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

Vm 21357/4014

9. DATE OF THE FIRST AUTHORISATION

First Authorisation 22nd May 1997

10. DATE OF REVISION OF THE TEXT

February 2010 (ATCVet code amended)