

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milk-Line Teat Plus 0.50% w/v Teat Dip / Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Qualitative composition</u>	<u>Quantitative composition</u>
Active substance:	
Available Iodine	0.50% w/v

Other relevant constituents:	
Glycerol	10.3 % w/v

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Teat dip / Teat Spray solution
A dark brown liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

As an aid in the prevention of mastitis in lactating dairy cattle.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

- i. Special precautions for use in animals

None.

- ii. Special precautions for the person administering the veterinary medicinal product to animals

The wearing of eye / face protection is recommended, when handling this product.

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

In case of ingestion, seek medical advice immediately and show this container or label.

When used as a spray, avoid working in the spray mist.

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

Do not eat, drink or smoke whilst using this product.

Keep away from food, drink and animal feedstuffs.

iii. Other precautions

For external use only.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

In laboratory animals, iodine compounds were not found to be tetraogenic and did not affect fertility. (CVMP iodine products summary report). May be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Incompatible with chlorhexidine digluconate based teat dips.

4.9 Amount(s) to be administered and administration route

Teat Dipping

Wash and dry teats and udders before milking. Immediately after each milking, dip each teat in undiluted Milk-Line Teat Plus using a teat dip cup. Make sure entire surface of teat is immersed in teat dip. Teat cups should be emptied after milking and washed before re-use.

Teat Spraying

Wash and dry teats and udders before milking. Immediately after each milking spray the teats with undiluted Milk-Line Teat Plus. Use the teat spray unit to spray the cows teats. Milk-Line Teat Plus should be only used in spray units producing a coarse spray. Spraying should give complete teat coverage.

Udder Washing

A solution of 75mls (3fl oz) of Milk-Line Teat Plus to 4 litres (1 gallon) of water should be used for disinfection.

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

Not applicable. Topical use only.

4.11 Withdrawal period(s)

Cattle: Meat – Zero days
Milk – Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Antiseptic and Disinfectant

ATC Vet Code:

QG52A

5.1 Pharmacodynamic properties

Iodine, formulated as an iodophor, belongs to the halogen group of disinfectants with an oxidising biocide action against a number of external mastitis pathogens.

5.2 Pharmacokinetic properties

Although there is some evidence that iodine is absorbed through the teat skin and enters the milk from the blood, the amount of absorption is minimal. Iodine residues in milk are not a problem in the UK. (In the 1996 ADAS report on Nutrient Analysis of Pasteurised Liquid Milk, National Survey 1995-96 was 31ug/100g).

5.3 Environmental properties

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Alcohol (C9-C11) 8 Mole Ethoxylate
Hydrogen Iodide
Hydrochloric Acid, concentrated
Water Deionised

6.2 Incompatibilities

Chlorhexidine Digluconate

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging of the 1000 litre container only:
6 months

6.4 Special precautions for storage

Do not store above 25°C.
Protect from direct sunlight.
Store in tightly closed original containers.
Protect from frost.
Store away from food, drink and animal feedstuffs.

6.5 Nature and composition of immediate packaging

Pack size: 20 L, 25 L, 200 L and 1000 L

Container: Natural or blue opaque high density polyethylene (HDPE) drums.

1000 L: Opaque white high-density polyethylene (HDPE) IBC

Closures: Opaque high density polyethylene (HDPE) cap (screw fit) for all pack sizes.

Ensure that all equipment and containers used for decanting contain not more than enough product for use that day and are fit for purpose, clean, emptied after use and washed before use.

Do not return used product to the original container.

The 1000 litre container is for use with in-place application systems only.

The 200 litre and 1000 litre containers should not be re-used or returned for re-filling. Not all pack sizes may be marketed.

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

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal product or waste material 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.

7. MARKETING AUTHORISATION HOLDER

Ecolab Ltd (Trading as Adams Healthcare)
Lotherton Way, Garforth
Leeds LS25 2JY
UK

8. MARKETING AUTHORISATION NUMBER

VM 04509/4011

9. DATE OF FIRST AUTHORISATION

Date: 13 June 2008

10. DATE OF REVISION OF THE TEXT

Date: February 2013

Approved:



08/02/2013