

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ready-To-Use Teat Dip / Teat Spray Solution, 0.538% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: 0.538% w/v minimum available Iodine
Other Constituents: 2% w/v Glycerol
For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Teat Dip / Teat Spray Solution
Description: Mobile brown 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.

Keep away from food, drink and animal feedstuffs.

Do not eat, drink or smoke while using the product.

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: Ready to use, no dilution necessary. The solution should be used direct from the container without dilution. Fill teat dipping cup approximately 2/3rds full and immediately after each milking dip each teat in the solution, ensuring that the entire surface of the teat comes into contact with the solution. Top up the cup with fresh solution if necessary. Discard soiled solution.

Teat Spraying: Immediately after each milking spray the entire surface of the teats with the full strength solution.

Udder Washing And Cluster Dipping: Prepare a fresh solution daily. Use in the proportion of 1 part Product with 80 parts water. Udder cloths should be allowed to soak in the solution. The use of separate cloths for each cow, or disposable paper towels is strongly recommended.

Teat clusters should be immersed and agitated for at least 30 seconds in the solution before milking each cow.

Prepare fresh dilutions daily. Discard any remaining diluted solution at the end of the day.

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

The product is an Iodine based teat dip belonging to the Iodophor group of disinfectants which acts by killing bacteria. Additionally the product contains humectants, which improve skin condition.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Alcohol (C9-C11) 6/7 mole ethoxylate
Water Potable

6.2 Incompatibilities

Do not mix with other chemicals. Dilute only with clean water.

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 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 white high density polyethylene bottles closed with white opaque high density polyethylene screw-fit caps.

20,25 and 200 litre natural or white high density polyethylene drums closed with white opaque high density polyethylene screw fit caps.

The 200 litre containers should not be returned for refilling.

Not all pack sizes may be marketed.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. 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 21357/4012

9. DATE OF THE FIRST AUTHORISATION

First Authorisation: 22nd June 1999

10. DATE OF REVISION OF THE TEXT

February 2010 (ATCVet code amended)