SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2:1 Iodine Concentrate 1.50% w/v, Teat Dip or Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: 1.50% w/v available Iodine

Other Constituents:
15.00% w/v Glycerol
0.50% w/v Ethoxylated Lanolin

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for 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 diluted 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

CONCENTRATE
The following safety phrases refer to the concentrated product only and do not apply once the product is diluted to the working solution: Risk of serious damage to eyes. Wear eye/face protection when preparing the dip or spray.

DILUTED WORKING SOLUTION
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 whilst 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

The product is a concentrated teat dip which when diluted 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. This concentrate requires dilution just prior to use.

Teat Dipping: The product should be diluted by adding 1 part of Concentrate to 2 parts of clean water. Immediately after milking fill a teat dipping cup two-thirds full with the diluted solution.
Dip the teats into the product ensuring complete coverage. Refill the teat cup as necessary. Discard soiled dip solution.

Teat Spraying: Prepare a solution by adding 1 part product to 2 parts clean water.

After each cow has been milked, spray the entire surface of each teat with the solution.
Wash teats and udders before next milking.

Udder Washing: When the teats are dirty clean them with a paper towel soaked in 25 ml of product in 8 litres of clean water. When mastitis is in the herd use 25 ml of product in 4 litres of clean water Prepare a fresh solution daily. Use one disposable paper towel for each cow

Cluster dipping: Between transferring clusters from one cow to the next, plunge the clusters 3 times into a solution prepared by adding 25 ml of teat dip concentrate to 8 litres of water.

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

Iodine is a halogen element being a member of Group VII of the Periodic Table. In common with other members of this group, notably chlorine, it is a broad-spectrum bactericide useful for skin disinfection.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Ethoxylated Lanolin
Alcohol 8 Mole Ethoxylate
Potable Water

6.2 Incompatibilities

Incompatible with Chlorhexidine-based teat dips.

6.3 Shelf life

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

6.4 Special precautions for storage

For one milking only when transferred to teat dip cup.
Dilute immediately before use, any unused diluted product should be discarded.
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.
Store upright, tightly closed in original container.
Store away from animal feed.

6.5 Nature and composition of immediate packaging

Available in;
5 or 25 litre natural or blue high density polyethylene drums closed with white high density polyethylene tamper evident caps.
200 or 1000 litre* blue or black high density polyethylene barrels closed with white screw top bungs with inside thread.
The 200 and 1000 litre containers should not be returned for re-filling.
Not all pack sizes may be marketed.

*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.

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 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

Vm 21357/4000

9. DATE OF THE FIRST AUTHORISATION

Date: 24 April 1992

10. DATE OF REVISION OF THE TEXT

Date: January 2013

Approved:
18/01/13