SUMMARY OF PRODUCT CHARACTERISTICS

1) Name of the veterinary medicinal product

EmpraSan Sovereign, 2.7% w/v, Teat dip solution

2) Qualitative and Quantitative composition

Active Substance: 2.7% w/v minimum available Iodine

Other Constituents:
12.15% w/v Glycerol
12.15% w/v Sorbitol Solution 70% (Non- crystallising)
For full list of excipients see section 6.1

3) Pharmaceutical form

Teat dip 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 is diluted and then 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.

Post-milking teat dipping / spraying: This concentrate requires to be diluted just prior to use. Prepare a solution of 1 part product to 4 parts clean water. Prepare a fresh solution daily. Fill the teat cup two thirds full with this solution. After each cow has been milked, dip each teat ensuring that the entire surface of the teat comes into contact with the solution. Refill the teat cup as necessary from the solution. Teat cups should be emptied after use and washed before re-use. Wash and dry teats and udders before next milking.

Spraying: Prepare a solution of 1 part product to 4 parts clean water. Prepare a fresh solution daily. After each cow has been milked, spray the entire surface of each teat with the solution. Wash and dry teats and udders before next milking.

Udder Washing And Cluster Dipping: Use in the proportion of 1 part product to 415 parts water. Udder cloths should be allowed to soak in the solution. The use of separate udder cloths for each cow, or disposable paper towels is strongly recommended. Teat clusters should be immersed and agitated for 10 seconds before milking each cow. Prepare a fresh teat dip solution daily.

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

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

The product is for external use only.

6) Pharmaceutical particulars

6.1 List of excipients

Glycerol
Sorbitol Solution 70% (Non- crystallising)
Alcohol (C_9-C_{11}) 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

For one milking only when transferred to teat dip cup.
Use diluted product immediately. Discard any remaining diluted solutions at the end of each day.
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 food, drink and animal feeding stuffs.

6.5 Nature and composition of immediate packaging

Available in;
5, 10, 20, 25 or 200 litre natural or white high density polyethylene bottle closed with white opaque high density polyethylene screw-fit caps.
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 veterinary medicinal product or waste materials 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 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
DG11 2SD

8) Marketing authorisation number

Vm 21357/4010

9) Date of the first authorisation

First Authorisation18th December 1992

10) Date of revision of the text

February 2009