Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Lanodip Concentrate Teat Dip Solution 2:1

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: Iodine Ph. Eur 20 mg (Available Iodine 15.9 mg)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat Dip Solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

An aid in the prevention of mastitis in dairy cattle.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Teat dip cups should be emptied after each milking and washed before re-use.

Wash and dry udder and teats with individual paper towels preferably before next milking.

4.5 Special precautions for use

Special precautions for use in animals:

None.

Special precautions to be taken by the person administering the veterinary medicinal product:

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

Wash hands after use.

When being applied through spray equipment the operator should avoid working in the spray mist. In case of contact with eyes give prolonged irrigation with clean water and seek medical attention. In case of ingestion seek medical attention immediately.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Lanodip Concentrate is a medical disinfectant intended for use on lactating and/or pregnant dairy cattle.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other products. Incompatible with Chlorhexidine based teat dips.

4.9 Amounts to be administered and administration route

For topical application to the teats and udder. This is a concentrated product, dilute before use.

Teat Dipping:

Prepare a stock solution of 1 part product to 2 parts water and mix thoroughly. A fresh stock solution must be prepared daily. Fill a teat dipping cup two thirds full and immediately after each cow has been milked dip each teat in the solution ensuring that the entire surface of the teat comes into contact with the solution. Refill the teat cup with the stock solution of Lanodip as necessary. Discard soiled teat dip solution. Wash teat cup after use. Wash teats before each milking.

Teat Spraying:

Prepare a stock solution of 1 part product to 2 parts water and mix thoroughly. A fresh solution must be prepared daily. After each milking spray the entire surface of each teat with stock solution of product. Wash teats before each milking.

Udder Washing:

Use 25 mls (1 fl. oz.) of product in 8.0 litres (2 gallons) of water to wash the teats and udder of each cow before milking. When mastitis is in the herd use 25 ml of product in 4 litres of clean water. Prepare a fresh solution daily. Use a separate cloth or preferably a disposable paper towel for each cow.

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

The product is applied externally.

4.11 Withdrawal Period(s)

Meat: 0 days. Animals intended for human consumption may be slaughtered following treatment.Milk: 0 days. Milk intended for human consumption may be taken from animals during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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.

ATC vet code: QD08AG Pharmaco-therapeutic Group: Antiseptics and Disinfectants

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyethylene 8-primary C9/C11 alcohol Polyethylene glycol 75 lanolin Propane 1.2-diol USP Sodium acetate Deionised water

6.2 Incompatibilities

Do not mix with chlorhexidine digluconate.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year. Use diluted product immediately.

6.4 Special precautions for storage

Store below 25°C. Protect from light. Protect from frost. Store away from animal feeds. Store upright, tightly closed in the original container.

6.5 Nature and composition of immediate packaging

HDPE containers containing 5, 20 or 25 litres. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

This product is harmful to fish. Care should be taken to ensure that neither waste product nor used containers enter waterways, ponds, ditches etc. Unused product or empty containers should be disposed of in accordance with guidance from an appropriate waste

7 MARKETING AUTHORISATION HOLDER

Kilco (International) Ltd. Broomhouses 2 Industrial Estate Old Glasgow Road Lockerbie DG11 2SD Scotland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10948/001/001

regulation authority.

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

August 2012