Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Lanodip Ready To Use Teat Dip

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Iodine6.7 mg(Available Iodine 5.1 mg)

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Teat Dip / Spray Solution. A dark 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.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.

4.4 Special warnings for each target species

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

Special precautions for use in animals

None.

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

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

Wash hands after use

When the product is being applied through spray equipment avoid working in 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

The product is a medicinal 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

Lanodip Ready To Use Teat Dip is a ready to use teat dip which 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.

Post-milking teat dipping:

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. Discard soiled teat dip solution. Teat cups should be emptied after use and washed before re-use. Wash teats and udders before each milking.

Spraying:

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

Udder washing:

When the teats are dirty clean them before milking with a paper towel soaked in 75 ml of product in 8 litres of clean water. When mastitis is in the herd use 75 ml of product in 4 litres of clean water Prepare a fresh solution daily. Use one disposable paper towel for each cow.

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

The product is applied externally to the teat surface only.

4.11 Withdrawal Period(s)

Meat and offal: zero days. Milk: zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, antiseptics and disinfectants, iodine products, iodine.

ATC vet code: QD08AG03

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

Polyoxyethylene 8-primary C9/C11 alcohol Polyethylene glycol 75 lanolin Propylene glycol Sodium acetate Deionised water

6.2 Incompatibilities

Do not mix with products that contain chlorhexidine digluconate.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The product is packaged in 5-litre and 25-litre HDPE containers.

Not all pack sizes may be marketed.

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

As the product is harmful to fish, care should be taken to ensure that neither waste product nor used containers enter waterways, ponds, ditches etc.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10948/001/004

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd June 2009

10 DATE OF REVISION OF THE TEXT

August 2012