Summary of the Product Characteristics (SPC) of

LANODIP GOLD TEAT DIP RTU

(Article 5a council directive 81/851/EEC as amended by guideline III/3322/92-Rev.3)

1 NAME OF THE VETERINARY MEDICINAL PRODUCT LANODIP GOLD TEAT DIP RTU

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Iodine 6.7mg/ml

3 PHARMACEUTICAL FORM

Teat Dip Solution

4 PHARMACOLOGICAL PROPERTIES

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

5. CLINICAL PARTICULARS

5.1 Target species

Cattle - lactating dairy

5.2 Indications for use, specifying the target species.

As an aid in the prevention of mastitis in lactating dairy cattle. The product is applied directly, after each milking, to the teats by spraying or dipping with a teat cup.

5.3 Contraindications

None

5.4 Undesirable effects (frequency and seriousness)

None

5.5 Special precaution(s) for use

For external use only.

5.6 Pregnancy or lactation

The product is safe to use on pregnant & lactating cows.

5.7 Interaction with other medicaments and other forms of interaction

Do not mix with other products.

Incompatible with Chlorhexidine-based teat dips.

5.8 Posology (dosage) and method of administration

The product 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 the product. After each cow has been milked, dip each teat ensuring that the entire surface of the teat comes into contact with the product. Refill the teat cup as necessary.. Teat cups should be emptied after use and washed before re-use. Wash and dry teats and udders before next milking.

Spraying

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

Udder washing

When the teats are dirty, clean them 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.

Cluster dipping.

Between transferring clusters from one cow to the next, plunge the clusters 3 times into a solution prepared by adding 75 ml of product to 8 liters of water.

If symptoms of disease persist consult a veterinary surgeon.

5.9 Overdosing (symptoms, emergency procedures, antidotes)

Not applicable.

5.10 Special warnings for each target species

Teat dip cups should be emptied after each milking and washed thoroughly before reuse.

Wash and dry udders and teats before next milking.

5.11 Withdrawal periods

Withdrawal period: Meat – Zero days Withdrawal period: Milk – Zero hours

5.12 Special precautions for person administering the product to animals

Do not eat, drink or smoke whilst using the product

Wash hands after use

Keep away from food, drink and animal feedingstuffs

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

Avoid contact with eyes

In case of contact with eyes, give prolonged irrigation with clean water and seek medical attention

In case of ingestion, seek medical attention immediately

6.0 PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities (major)

Chlorhexidine Digluconate

6.2 Shelf life

1 year

6.3 Special precautions for storage

Do not store above 25°C
Protect from frost
Discard any soiled teat dip at the end of each day
Protect from light
Store away from food, drink or animal feedingstuffs

6.4 Nature and contents of container

The product is packed in a 5, 25 or 200Litre HDPE containers.

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from such veterinary medicinal products.

Any unused product or waste material should be disposed of in accordance with national requirements. To dispose of unused product to land, you must have 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.

Name or corporate name and address or registered place of business of the marketing authorisation holder.

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Additional Information

Date of First Authorisation/Last Renewal Marketing Authorisation Number Conditions of supply of Veterinary Medicinal Product Date of revision of the text May 1997/March 2007 01936/ 4007 GSL April 07