

**IRISH MEDICINES BOARD ACT 1995**

**MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998**

**(S.I. No.142 of 1998)**

**10845/002/001**

Case No: 7002585

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Dairygold Co-op Society Ltd.**

**West End, Mallow, Co. Cork, Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**SuperGold Chlorhexidine Ready to Use Teat dip/spray 0.5%w/v**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **20/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Super Gold Chlorhexidine Ready To Use Teat Dip / Spray 0.5% w/v

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active Substance

Chlorhexidine gluconate 0.5% w/v  
(as Chlorhexidine gluconate solution)

##### Excipients

For a full list of excipients, see Section 6.1

#### 3 PHARMACEUTICAL FORM

Teat Dip solution/spray

#### 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 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 thoroughly before re-use.

## 4.5 Special precautions for use

### Special precautions for use in animals

- a) wash and dry udder and teats with an individual paper towel preferably before the next milking
- b) teat dip cups should be emptied after milking and washed before re-use
- c) for external use only
- d) if signs of disease persist or appear consult your veterinary surgeon

### 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.
- When the product is being applied through spray equipment the operator should avoid working in the spray mist.
- Avoid contact with eyes. In case of contact with eyes, give immediate prolonged irrigation with clean running water and seek medical attention.
- In case of ingestion, seek medical attention immediately.
- Keep away from food, drink and animal feedingstuffs.
- Wash hands after use.

## 4.6 Adverse reactions (frequency and seriousness)

Skin sensitivity to Chlorhexidine is rare and no suspected adverse reactions have been reported.

## 4.7 Use during pregnancy, lactation or lay

The product is a medicinal disinfectant intended as an aid against mastitis. It is safe to be used on lactating and pregnant cows and is applied externally without risk to the cow.

## 4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other products. This product is incompatible with soaps and other anionic materials.

#### 4.9 Amounts to be administered and administration route

The product is a ready-to-use teat dip that 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.

##### Teat dipping

The product should be used directly from the container without dilution.

Fill a teat cup two thirds full with the product.

Dip teats of every cow immediately after milking ensuring that the full length of each teat is dipped.

Refill the cup as necessary.

Discard soiled teat solution.

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

Wash and dry the udders and teats before next milking.

##### Teat spraying

The product should be used directly from the container without dilution.

Spray the full length of each teat after milking. Apply immediately after each milking.

Wash and dry the udders and teats before next milking.

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

Not applicable. The product is applied externally to the teat surface only.

#### 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 following treatment.

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code QD08AC02

#### 5.1 Pharmacodynamic properties

Chlorhexidine gluconate belongs to a group of cationic materials e.g. benalkoniumchloride, cetrimide, cetylpyridinium.chloride and domiphenol bromide.

Chlorhexidine is a cationic disinfectant and bactericide against many gram positive and gram negative micro-organisms.

When used on cows teats and udders this product aids in the prevention of mastitis and in the prevention/healing of teat lesions.

Any dryness or skin irritation, which may be caused by the activity of the bactericide, is eliminated by the addition of glycerine as an emollient.

#### 5.2 Pharmacokinetic properties

Chlorhexidine Gluconate is poorly absorbed through skin and is readily eliminated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Alcohol 8 mole ethoxylate

Isopropyl Alcohol

Glycerol

Ethoxylated Lanolin

Sodium Acetate Trihydrate

Ponceau 4R (E124)

Deionised Water

### **6.2 Incompatibilities**

Chlorhexidine gluconate is incompatible with soaps. Do not mix with other products normally available on the farm.

### **6.3 Shelf-life**

12 months

### **6.4 Special precautions for storage**

- Store upright, tightly closed in the original containers.
- Do not store above 25°C
- Protect from light.
- Protect from frost. If the contents freeze it is important that are thoroughly thawed and mixed before use.

### **6.5 Nature and composition of immediate packaging**

The product is packed in a 5, 20, or 25 Litre HDPE containers, with polypropylene/polyethylene or high density polyethylene caps.

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

The product is harmful to fish and aquatic life. 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 regulatory authority.

**7 MARKETING AUTHORISATION HOLDER**

Dairygold Co-operative Society Ltd.  
West End,  
Mallow,  
County Cork,  
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10845/2/1

**10 DATE OF REVISION OF THE TEXT**