

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Clinidip L Concentrate 2.0 % w/v Concentrate for Teat dip or teat spray, solution

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Active Ingredient:

Iodine (available) 2.00 % w/v

Made from iodophor concentrate to give the appropriate level of available iodine.

#### Other constituents:

Glycerol 10.0 % w/v

Peg 75 lanolin 2.7 % w/v

For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Concentrate for Teat Dip/Teat Spray solution

Liquid with the brown colour and smell typical of iodine products.

### **4. CLINICAL PARTICULARS**

The product is a bactericidal disinfectant containing iodine as the active agent. Iodine has a unique elemental bactericidal effect under acidic conditions.

#### **4.1 Target species**

Lactating dairy cows, sheep and goats

#### **4.2 Indications for use, specifying the target species**

When used as a teat dip / teat spray is an aid in the prevention of the spread of mastitis in lactating dairy cattle, sheep and goats.

#### **4.3 Contraindications**

None.

#### **4.4 Special warnings for each target species**

For external use only.

#### **4.5 Special precautions for use**

- i. Special precautions for use in animals

Wash and dry udders and teats before next milking. Empty teat dipping beakers after each milking and wash before reuse.

- ii. Special precautions for the person administering the veterinary medicinal product to animals

##### **CONCENTRATE**

The following safety phrases relate 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 used as a spray, avoid working in a 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.

Do not eat, drink or smoke while using this product.

Keep away from food, drink and animal feedstuffs.

- iii. Other precautions

None

#### **4.6 Adverse reactions (frequency and seriousness)**

No adverse reactions have been reported in similar iodine/iodophor based products.

#### **4.7 Use during pregnancy, lactation or lay**

Safe for use in pregnant and lactating cows, sheep and goats. The product is a medicinal disinfectant for external application as an aid against mastitis.

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

Do not use in conjunction with any other treatment for disinfection of teats/udders — not compatible with chlorhexidine based teat dips. No practitioner has advocated that daily use of iodine based teat dips should cease when other medicinal measures are being taken.

#### **4.9 Amount(s) to be administered and administration route**

*Clinidip L Concentrate is a teat dip/teat spray preparation that needs dilution prior to use.*

Clinidip L Concentrate is a preparation that should be diluted prior to use. Make up a stock solution daily by diluting 1 part Clinidip L Concentrate with 3 parts clean water, e.g. 5 litres preparation becomes 20 litres stock solution. The stock solution will contain 5000 ppm iodine. Discard any remaining diluted stock solution at the end of the day.

### **Teat Dipping**

Fill the dipping beakers two thirds (2/3) full and apply to the teats of the lactating cows, sheep or goats immediately after milking. The dipping beakers should be emptied after each milking and washed before reuse. Replenish dipping beakers after each milking.

### **Teat Spraying**

Immediately after the milking of cows, sheep or goats spray the entire surface of each teat.

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

Not applicable — external teat surface treatment only.

## **4.11 Withdrawal period(s)**

Meat: Zero days and Milk: Zero hours

## **5. PHARMACOLOGICAL PROPERTIES**

### **Pharmacotherapeutic group:**

Products for teats and udder, Disinfectants

### **ATC Vet Code: QG52A**

Iodine, formulated as an iodophor, is a halogen with an oxidising biocidal action against most mastitis pathogens.

Veterinary Disinfectant: Dermatologicals: Antiseptics and disinfectants. Iodine

## **5.1 Pharmacodynamic properties**

The active ingredient is a disinfectant with bactericidal activity against most bacteria. The post milking topical application of the product to the teats of lactating cows, sheep and goats prevents the ingress of pathogenic organisms into the streak canal of the teat and thereby aids in the prevention of the spread of mastitis from infected quarters to non-infected quarters.

## **5.2 Pharmacokinetic properties**

Although there is some evidence that iodine may be absorbed through teat skin, most iodine in milk is from dietary sources. Iodine has been determined in milk principally as the iodide. In the UK, the Committee on Toxicity of Chemicals in Food, Consumer Products concluded that the concentrations of iodine in cows'

milk are unlikely to pose a risk to health after the determination of iodine levels in milk in 1998/9.

The Committee for Veterinary Medicinal Products (CVMP) has concluded that it would be inappropriate to elaborate Maximum Residue Limits (MRLs) for iodine and that iodine should therefore be included in Annex II of Council Regulation 2377/90/EEC (CVMP, 1996; Annex E).

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Glycerol  
Peg 75 Lanolin  
Alcohol 6 mole ethoxylate  
Ethylene oxide: propylene oxide block co-polymer  
Alcohol 6 mole ethoxylate:3 mole propoxylate co-polymer  
Water Potable

### **6.2 Incompatibilities**

Iodine based teat dips are not compatible with chlorhexidine based products, hypochlorite solutions and other oxidizing agents and alkaline soaps and detergents

### **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 20 °C.  
Protect from frost.  
Protect from direct sunlight.

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

Available in:

1. 25 and 45 litre natural, high density polyethylene containers closed with high density polyethylene screw-fit tamper evident caps with expanded polyethylene foam washers.
2. 200\* litre blue, high density polyethylene drums closed with polypropylene tamper evident bungs.

\*The 200 litre containers should not be returned for re-filling.

Not all pack sizes may be marketed.

**6.6 Special precautions for the disposal of unused veterinary medicinal product 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 2009.

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

**7. MARKETING AUTHORISATION HOLDER**

GEA FARM TECHNOLOGIES (UK) LTD  
Wylle Works  
Watery Lane  
Bishopstrow  
Warminster  
Wiltshire  
BA12 9HT

**8. MARKETING AUTHORISATION NUMBER**

Vm 01808/4010

**9. DATE OF FIRST AUTHORISATION**

28th August 1992

**10. DATE OF REVISION OF THE TEXT**

July 2018

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Approved 25 July 2018