

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinidip 2.5 % w/v Superconcentrate
Concentrate for Teat Dip or Teat Spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Iodine (available) 2.50 % w/v

Other constituents:

Glycerol 20.0 % w/v

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for Teat Dip or Teat Spray solution

To be diluted prior to use.
A viscous liquid with the colour and smell typical of iodine.

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.
Clinidip Superconcentrate Teat Dip is a preparation that should be diluted prior to use. Prepare fresh solutions daily.
Discard any remaining diluted stock solution at the end of the day.
Empty teat dipping beakers after each milking and wash before reuse.

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

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 Superconcentrate Teat Dip is a preparation that should be diluted prior to use which is for the external application to the teats of lactating cows, sheep and goats.

Teat Dipping

Make up a stock solution daily by diluting 1 part of CLINIDIP Superconcentrate Teat Dip with 4 parts of water. The stock solution will contain 5000 ppm iodine. 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

Make up a stock solution daily by diluting 1 part of CLINIDIP Superconcentrate Teat Dip with 4 parts of water. The stock solution will contain 5000 ppm iodine. 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

Clinidip Superconcentrate is a concentrated teat dip/spray containing iodine (as an iodophor) and emollients as an aid in the prevention of the spread of mastitis in lactating dairy cattle, sheep and goats. Clinidip Superconcentrate must be diluted before use.

6.1 List of excipients

Glycerol
Peg 75 Lanolin
Alcohol 6 mole ethoxylate
Ethylene oxide: propylene oxide block copolymer
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 oxidising 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

Do not store above 20 °C.
Protect from frost.
Protect from direct sunlight.
Discard any remaining diluted stock solution at the end of the day.

6.5 Nature and composition of immediate packaging

Clinidip Superconcentrate Teat Dip is packed in:

1. 5 litre high density polyethylene jerricans closed with high density polyethylene screw-fit tamper evident caps.
2. 20, 25 and 45 litre natural, high density polythene containers closed with high density polyethylene screw-fit tamper evident caps with expanded polyethylene foam washers.
3. 200* litre blue, high density polyethylene drums closed with polypropylene tamper evident bungs.

* The 200 litre containers should not be returned for refilling.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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
Wylde Works
Watery Lane
Bishopstrow
Warminster
Wiltshire
BA12 9HT

8. MARKETING AUTHORISATION NUMBER

Vm 01808/4011

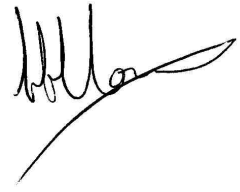
9. DATE OF FIRST AUTHORISATION

28 August 1992

10. DATE OF REVISION OF THE TEXT

July 2018

Revised: July 2018
AN: 00525/2018

A handwritten signature in black ink, consisting of several loops and a long, sweeping tail that curves downwards and to the right.

Approved 25 July 2018