

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dairyclene Iodine 2% w/v Concentrate for Teat Dip and Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active substances</u>	<u>%w/v</u>
Iodine	2.0

<u>Other relevant constituents</u>	
Glycerol	15.82
Sorbitol Solution 70%w/w (Non crystallising)	15.82

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for Teat Dip/Teat Spray solution
A clear homogeneous dark brown liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle – milking cows

4.2 Indications for use, specifying the target species

A dilutable teat dip/spray as an aid in the control of bovine mastitis.

4.3 Contraindications

Not applicable

4.4 Special warnings for each target species

None

4.5 Special precautions for use

- i. Special precautions for use in animals

Wash and dry udders and teats before milking.
Teat dip cups should be emptied after milking and washed before re-use.

These are both important aspects of good hygiene and mastitis

control.
For external use only.

- 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 using as a spray, avoid working in 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 label. Hands and exposed skin should be washed after using this product. Do not eat, drink or smoke while using the product. Keep away from food, drink and animal feedstuffs.

- iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Very rare - change of active ingredient teat dip type can on very rare occasions cause skin irritation.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

The use of the product has no known interactions with other products, including cow diet supplements.
Do not mix with other chemicals.

4.9 Amount(s) to be administered and administration route

This product is diluted before use. Prepare a fresh solution daily.

Teat dipping:

Add 1 part product to 3 parts of clean water and mix well.

Directly after milking each cow, dip the full length of each teat in the product.

The teat cup should be kept topped up as necessary.

Teat spraying:

Add 1 part product to 4 parts of clean water and mix well.

Directly after milking each cow, spray the entire surface of each teat with the product.

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

Not applicable for the intended mode of application.

4.11 Withdrawal period(s)

Withdrawal period for meat/milk - zero days/hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Teat dips

ATC Vet Code: QD08AG53

5.1 Pharmacodynamic properties

Iodine based teat dips have broad spectrum antibacterial action against mastitis causative organisms. The microbiological action of iodine appears to be due to an oxidative – reductive reaction involving various cell wall constituents which are irreversibly transformed. It appears sulphhydryl linkages, in bacterial cell wall components are specifically targeted by the iodine.

5.2 Pharmacokinetic properties

The absorption of iodine through the skin from teat dipping applications is well below levels which would indicate pharmacokinetic activity of the type described in the committee for veterinary medicinal products summary report on iodine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol solution 70% w/w (non crystallising)
Alcohol (C13-C15) 12 mole ethoxylate
Citric acid monohydrate
Sodium hydroxide
Sulphuric acid (for pH adjustment)
Water deionised

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from direct sunlight.
Store in tightly closed original container.
Protect from frost.
Discard any remaining unused, diluted product.

6.5 Nature and composition of immediate packaging

20 litre, blue or white opaque, high density polyethylene drum, with a black high density polyethylene cap (screw fit, tamper evident) with expanded polyethylene gasket.
200 litre, blue, opaque, high density polyethylene drum, with a white polypropylene cap (screw fit, tamper evident), with ethylene propylene dienterpolymer washer.
The 200 litre container 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

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. 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 1998.

7. MARKETING AUTHORISATION HOLDER

Diversey Limited
Weston Favell Centre
Northampton
NN3 8PD

8. MARKETING AUTHORISATION NUMBER(S)

Vm 15985/4031

9. DATE OF FIRST AUTHORISATION

Date: 22 June 2005

10. DATE OF REVISION OF THE TEXT

Date: October 2011