

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dairyclene Chlorhexidine Gluconate 0.425 % w/w RTU Teat Dip and Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	% w/w
Chlorhexidine Gluconate (as chlorhexidine gluconate solution)	0.425
Excipients	
Ponceau 4R (E124)	0.001
Other relevant constituents	
Glycerol	3.00

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Teat dip and teat spray solution.
Opaque, pink liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle – milking cows

4.2 Indications for use, specifying the target species

A ready to use teat dip/spray solution for use 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

For external use only

Wash and dry udders and teats before milking

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

Avoid contact with eyes. In the case of contact with eyes rinse with clean running water immediately.

When used as a spray, avoid working in spray mist.

In case of ingestion seek medical attention immediately.

Do not eat, drink or smoke whilst using the product.

Keep away from animal feed.

Wash hands after use.

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

Use as required

4.8 Interaction with other medicinal products and other forms of interaction

This disinfectant is inactivated by soaps and anionic disinfectants

4.9 Amount(s) to be administered and administration route

This product is used without dilution.

Teat Dipping

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

Replenish the teat dip cup as necessary.

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

Spraying:

Immediately after milking, 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)

Meat – zero days.

Milk – zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Products for teats and udder, Disinfectants

ATC Vet Code: QG52A

Antiseptics

5.1 Pharmacodynamic properties

Chlorhexidine is recognised as a broad spectrum biocide active against common mastitis causing bacteria. The mode of action involves rapid attraction to the bacterial cell wall and absorption to phosphate compounds on the bacterial surface.

5.2 Pharmacokinetic properties

Because of its cationic nature, chlorhexidine bonds strongly to skin and mucosa. It is therefore poorly absorbed after oral or topical application. Chlorhexidine is of low toxicity. Residues in milk from use as a teat dip or spray have been demonstrated to be low.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ponceau 4R (E124)

Glycerol

Paraffin Liquid Light

Isotridecanol 8 mole ethoxylate

Isotridecanol 12 mole ethoxylate

Alcohol (C13-15) 3 mole ethoxylate

Isopropyl alcohol

Water, deionised

6.2 Incompatibilities

Chlorhexidine is incompatible with soaps and other anionic materials.
Do not mix with other chemicals or teat dips.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
2 years

6.4 Special precautions for storage

Do not store above 25°C.
Protect from frost
Protect from direct sunlight
Store in tightly closed original container

6.5 Nature and composition of immediate packaging

20 litre blue, white or natural opaque high density polyethylene drum with black high density polyethylene cap (tamper evident) with expanded polyethylene gasket.

25 litre white high density polyethylene drum with black high density polyethylene cap (tamper evident).

200 litre blue high density polyethylene drum with white co-polymer polypropylene bung.

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 the local requirements.

To dispose of any unused product to land you must have an 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.

7. MARKETING AUTHORISATION HOLDER

Diversey Limited
Weston Favell Centre
Northampton
NN3 8PD

8. MARKETING AUTHORISATION NUMBER(S)

Vm 15985/4030

9. DATE OF FIRST AUTHORISATION

Date: 14th March 2005

10. DATE OF REVISION OF THE TEXT

Date: October 2011