

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MV Chlorhexidine (0.425% w/w) RTU Teat Dip and Teat Spray solution

2. QUANTITATIVE AND QUALITATIVE COMPOSITION

Active ingredient	% w/w
Chlorhexidine Gluconate solution (as chlorhexidine gluconate solution)	0.425

Excipients	% w/w
Ponceau 4R (E124)	0.000875

Other Relevant Constituents	% w/w
Glycerol	3

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Teat Dip / Teat Spray solution
Pink opaque liquid
pH 6

4. CLINICAL PARTICULARS

4.1 Target Species

Bovine animals (cows)

4.2 Indications for use

A ready to use teat dip/spray for use as an aid in the control of bovine mastitis in cattle

4.3 Contra-indications

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 to be taken by the person administering the medicinal product to animals

Avoid contact with eyes. If splashed in the eye, rinse with clean running water immediately .

In case of ingestion seek medical attention immediately.

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

Keep away from animal feed.

Wash hands after use.

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 Amounts to be administered and administraton 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

Not applicable for the intended mode of application.

4.11 Withdrawal period

Meat- zero days, milk- zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Products for teats and udder, Disinfectants
ATCVet code: QG52A

Therapeutic group, teat dips

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 and absorption to phosphate compounds on the bacterial surface.

5.2. Pharmacokinetic particulars

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 teatdip or spray have been demonstrated to be low.

6. PHARMACEUTICAL PROPERTIES

6.1 List of Excipients

Ponceau 4R (E124)
Glycerol
Liquid paraffin 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

High density polyethylene 20 litre container with tamper evident polyethylene screw cap.
200* litre high density polyethylene container, with polypropylene copolymer bung.

* The 200 litre container should not be returned for re-filling.
Not all pack sizes may be marketed.

6.6 Special Precaution for disposal of unused medicinal product or waste materials if any,

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. NAME AND ADDRESS OF AUTHORISATION HOLDER

Diversey Limited
Weston Favell Centre
Northampton
Northamptonshire
NN3 8PD

8. MARKETING AUTHORISATION NUMBER

Vm 15985 / 4032

9. DATE OF FIRST AUTHORISATION

5 June 2007

10. DATE OF ANY REVISION OF TEXT

February 2012