

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MV Iodine (0.52% w/v) RTU Teat Dip and Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Available Iodine 0.52% w/v

Excipients:

For full list of excipients, see section 6.1

Other Relevant Constituents

| Active ingredient | %w/w |
|--------------------------|-------------|
| Glycerol | 10 |

3. PHARMACEUTICAL FORM:

Teat Dip/Teat Spray Solution.
Clear dark brown liquid.
pH 4

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle – milking cows

4.2 Indications for use

A ready to use 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

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.

4.5 Special Precautions for use

- i. Special precautions for use in animals

For external use only

- ii. Special precautions to be taken by the person administering the medicinal product to animals

When used as a spray avoid working in spray mist.
Do not eat, smoke or drink while using the product.
Wash hands and exposed skin after use.
Avoid contact with eyes .In the case of contact with eyes rinse with clean water for at least 10 minutes and seek medical advice immediately.
In case of ingestion , seek medical attention immediately.
Keep away from food, drink and animal feed.

4.6 Adverse reactions

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 Amounts to be administered and administration route

The product is used without dilution.

Teat dipping:

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:

Directly after milking each cow, 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/Milk: Zero hours/days.

5. PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: Products for teats and udder, Disinfectants

ATCVet code: QG52A

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 particulars

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
sodium iodide
linear alcohol ethoxylate
citric acid monohydrate
sodium hydroxide
sulphuric acid
water deionised

6.2 Incompatibilities

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

6.3 Shelf Life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of the intermediate packaging

Brown liquid in either 20, 25, 200* litre or 1000* litre blue or white high density polyethylene containers, closed with high density white polypropylene or black polyethylene screw fit, tamper evident caps. Not all pack sizes may be marketed.

*The 200 litre and 1000 litre containers should not be returned for re-filling.

For the 1000 litre presentation ensure that all equipment and containers used for decanting not more than enough product for use that day, are fit for purpose, clean, emptied after use and washed before re-use.

6.6 Special Precautions for the disposal of unused veterinary medicinal products 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 2009.

7. MARKETING AUTHORISATION HOLDER

Diversey Limited
Weston Favell Centre
Northampton
NN3 8PD

8. MARKETING AUTHORISATION NUMBER

Vm 15985/4033

9. DATE OF FIRST AUTHORISATION

Date: 04 March 2008

10. DATE OF THE REVISION OF THE TEXT

Date: November 2012

Approved:  **29/11/2012**