1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASODINE RTU 0.54% w/v TEAT DIP AND SPRAY SOLUTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Iodine	0.54% w/v

For full list of excipients see 6.1

3. PHARMACEUTICAL FORM

Teat Dip/Teat Spray solution.
Dark brown aqueous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dairy cows

4.2 Indications for use, specifying the target species

As an aid in the control of mastitis in lactating dairy cows, and in the prevention and healing of cracked and chapped teats.

4.3 Contraindications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

None

i. Special precautions for use in animals

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

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

Avoid contact with eyes. If splashed in the eyes rinse with clean running water and seek medical advice.

In case of ingestion seek medical attention immediately

When used as a spray, avoid working in a spray mist.
Do not eat, drink or smoke whilst using this product

Wash hands after use

4.6 Adverse reactions (frequency and seriousness)

Iodophor teat disinfectants can be regarded as safe for the dairy cow when used as recommended. At the concentrations used for post milking teat sanitation (5000ppm) their local and resorptive tolerance is good. In the rare case of a suspected or proven allergy in the herd, it is recommended to change to a non-iodine teat disinfectant.

4.7 Use during pregnancy, lactation or lay

The product is safe to use on pregnant and lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amount(s) to be administered and administration route

Teat dipping
Fill teat dip cup about two thirds full with the undiluted product and dip the teats immediately after each cow is milked. Top up the cup with the product as necessary.

Teat spraying
Immediately after milking, spray the entire surface of each teat with the solution.

Udder washing and cluster dipping
Use in the proportion 1 part to 80 parts clean water, i.e. 125ml in 10 litres or 2 fl.oz. in gallon. Udder cloths should be allowed to soak in the solution. The use of separate udder cloths for each cow is strongly recommended. Teat clusters should be immersed and agitated for at least 30 seconds before milking each cow. Rinse in clean water before use.

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

Not applicable

4.11 Withdrawal period(s)

Milk: Zero hours
Meat: Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

ATC Vet Code: QD 08AG03

5.1 Pharmacodynamic properties

Iodine has powerful bactericidal action and is used for disinfecting unbroken skin before operation. It is also active against fungi, viruses, protozoa, cysts and spores. It is generally employed as a disinfectant for human skin application as a 2% or 2.5% solution of iodine. The germicidal activity is reduced in the presence of organic matter although the reduction is reported to be less than that observed with other halogen disinfectants.

5.2 Pharmacokinetic properties

Absorption
When taken by mouth, iodine preparations (which are converted to iodide) and iodides are trapped by the thyroid gland. Iodine is slightly absorbed when applied to the skin. Solutions of iodine applied to the skin should not be covered with occlusive dressings.

Distribution and Elimination
Iodides not taken up by the thyroid are excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and sweat. They cross the placenta and are excreted in breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydroxide
Alcohol ($C_{13}C_{15}$) 11 Mole Ethoxylate
Sorbitol
Glycerol
Hydriodic Acid
Sodium Sulphate
Water Potable

6.2 Incompatibilities

1. Hypochlorite solutions and other oxidising agents
2. Phenolic/Soap/Pine oil disinfectants
3. Chlorhexidine teat disinfectants
4. Alkaline soaps and detergents

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polyethylene 60 and 200 litre drum with polypropylene co polymer bung and overseals.

25 litre white, natural or black high density polyethylene drum with high density polyethylene screw cap (tamper evident).

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 empty 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

Evans Vanodine International Plc
Brierley Road
Walton Summit
Preston
Lancashire
PR5 8AH

8. MARKETING AUTHORISATION NUMBER

Vm 03940/4009

9. DATE OF FIRST AUTHORISATION

6 January 1992

10. DATE OF REVISION OF THE TEXT

March 2016

Approved: 16 March 2016