

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Masodine RTU contains 0.54% w/v available Iodine and 5% W/V Glycerol and Sorbitol.

Iodine, Glycerol and Sorbitol.

4. PHARMACEUTICAL FORM

Teat dip/spray solution.

5. PACKAGE SIZE

25,60,200, Litres.

Additional wording required on 200 label

200 litre label: This container should only be used once and should not be returned for re-filling.

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. CONTRAINDICATIONS

None identified.

1. 8. ADVERSE REACTIONS

None.

2. 9. TARGET SPECIES

Dairy cows.

3. 10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

5,000 ppm minimum available Iodine when used undiluted as a teat dip or spray.

TEAT DIPPING

Fill teat cup about two-thirds full with **Masodine RTU**. Dip teats of every cow immediately after each has been milked, making sure that the full length of the teat is immersed. Top up with fresh solution as required. Empty and wash out cups after milking.

TEAT SPRAYING

Immediately after milking, spray the entire surface of each teat of every cow with **Masodine RTU**.

UDDER WASHING & CLUSTER DIPPING 62.5 ppm minimum available Iodine when diluted 1:80.

Dilute in the proportion 1 part to 80 parts clean water (2fl.oz per gallon or 125 ml per 10 litres.)

To help prevent cross infection, individual cloths or disposable paper towels are strongly recommended. Dry teats before milking. Immerse clusters and agitate for at least half a minute. Rinse in clean water before use.

11. ADVICE ON CORRECT ADMINISTRATION

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.

Wash and dry teats before milking.

Do not eat, drink or smoke whilst using this product

Wash hands after use.

12. WITHDRAWAL PERIOD

Milk: Zero hours.

Meat: Zero days.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in the original container. Keep the container tightly closed.

Protect from frost.

Keep away from animal feed.

14. SPECIAL WARNING(S)<User Warnings>

For animal treatment only. For external use only. Keep out of reach of children.

If signs of disease persist or appear, consult your veterinary surgeon.

15. EXPIRY DATE

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. To dispose of unused product to land you must have an authorisation under the Groundwater Regulations 1998.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

2009

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

[Distribution category]

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

20. MARKETING AUTHORISATION NUMBER(S)

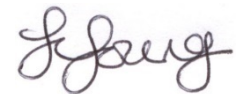
Vm <number>

Vm03940/4009

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION>

Approved: 25/07/2017

A handwritten signature in black ink, appearing to read 'J. J. J.', is written below the approval date.