

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 1:3 2.15% w/v CONCENTRATE FOR TEAT DIP AND SPRAY SOLUTION

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

Iodine, Glycerol and Sorbitol.

4. PHARMACEUTICAL FORM

Concentrate for teat dip/spray solution.

Masodine® 1:3 2.15% w/v concentrate for teat dip and spray solution contains 2.15% w/v AVAILABLE IODINE and 2% w/v GLYCEROL and 18% w/v SORBITOL. 5,000 ppm available Iodine minimum when diluted 1:3 as a teat dip or spray. 40 ppm available Iodine minimum when diluted 1:500 as udderwash or cluster dip.

UK authorised veterinary medicine
Economical concentrated iodophor formulation
Effective aid in the control of mastitis
Use as a post-milking dip or spray at full dilution rate of 1:3
May also be used for dipping pre-milking or as a spray at a rate of 1:7

Application Pre and post-milking teat dip/spray
Key ingredients Iodine, emollients

Masodine 1:3 2.15% w/v concentrate for teat dip and spray solution contains nonionic surfactant

Product information

An iodophor-based teat dip and spray which has been specially formulated to help reduce the bacterial contamination that causes mastitis in dairy herds. Reduces the risk of infection by leaving an antiseptic film or iodine adhering to teats which been treated by dipping or spraying. Contains 20% glycerol and sorbitol (5% when diluted) to help keep teats soft and supple, and to aid in the prevention and healing of sores and cracks.

5. PACKAGE SIZE

5,25,60,200,1000 Litres.

Additional wording required on 200 and 1000 litre labels:

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

1000 litre label: This container should only be used once and should not be returned for re-filling. 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. 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

8. ADVERSE REACTIONS

9. TARGET SPECIES

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

Teat dip or spray (5,000 ppm available iodine)

Dilute one part with three parts clean water and mix well.

Teat dipping Fill teat cup about two-thirds full with the prepared solution. 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 prepared solution.

Udder wash and cluster dip (40 ppm available iodine)

Dilute one part with 500 parts clean water (20 ml to 10 litres or 1 fl oz in 3 gal).

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. Wash and dry udders and teats before milking.

Alternative usage: Pre-milking disinfection (2,500 ppm available iodine)

Dilute one part with seven parts clean water and mix well. Make sure udder and teats are clean and dry before disinfection.

Pre-milking dipping Fill teat dipping cup 2/3 full with the 1 to 7 solution. Dip teats of every cow making sure that the full length of the teat is immersed. Allow 15 seconds contact time, then using a single service paper towel, wipe and dry teat thoroughly, before continuing with normal milking routine. Top up with fresh solution as required. Empty and wash out cups after milking.

Pre-milking spraying Spray the entire surface of each teat of every cow with 1 to 7 solution. Allow 15 seconds contact time, then using a single service paper towel, wipe and dry teat thoroughly, before continuing with normal milking routine.

11. ADVICE ON CORRECT ADMINISTRATION

CONCENTRATE

The following safety phrases relate to the concentrated product only, and do not apply once the product is diluted to the working solution:

Risk of serious damage to eyes. Wear eye/face protection when preparing the dip or spray.

DILUTED WORKING SOLUTION

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

Avoid contact with eyes.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed, seek medical advice immediately and show this label.

Hands and exposed skin should be washed after using this product.

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

Keep away from food, drink and animal feedstuffs.

12. WITHDRAWAL PERIOD

Milk: Zero hours.

Meat: Zero days.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in the original tightly closed container.

Protect from frost.

Diluted product should not be stored above 25°C.

Protect from light.

Once diluted use the product within 3 months.

Store diluted product only in glass or plastic containers.

14. SPECIAL WARNING(S)<User Warnings>

For animal treatment only. For external use only. Keep out of the sight and 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

22 March 2016

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”

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

Vm 03940/4006

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION>

Approved: 05/07/217

