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

Masocare 1:4 2.72% w/v concentrate for teat dip and spray solution

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

lodine, Glycerol and Sorbitol.

4. PHARMACEUTICAL FORM

This product contains as active ingredient 2.72% w/v AVAILABLE IODINE and also contains 42.5% w/v GLYCEROL and 2.5% w/v SORBITOL. 0.5% w/v available lodine when diluted 1:4 as a teat dip or spray. 0.005% w/v available lodine when diluted 1:400 as udderwash or cluster dip.8.5% w/v GLYCEROL and 0.5% w/v SORBITOL when diluted 1:4 as a teat dip or spray. Masocare 1:4 2.72% w/v Concentrate for Teat Dip and Spray Solution contains Nonionic Surfactant.

UK Authorised Veterinary Medicine.
Concentrate high emollient formulation.
Fast acting iodophor formulation.
Effective aid in the control of mastitis
Helps to prevent and heal chaps and sores.

Application Post-milking teat dip/spray Key ingredients lodine, emollients

Product information

An iodophor-based solution 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 of iodine adhering to teats which been treated by dipping or spraying. Contains high levels of glycerol and sorbitol to help in the healing of cracks and sores and to keep teat skin soft and supple all year round

5. PACKAGE SIZE

5,25,60,200 and 1000L

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 lodine)

Teat dipping

Fill teat cup about two-thirds full with the prepared solution and dip the teats of every cow immediately after milking ensure the full length of the teat is covered. Top up cup with fresh solution as required. Teat dip cups should be emptied and washed after milking.

Teat spraying

Immediately after milking, spray the entire surface of each teat of every cow with the prepared solution.

Udder wash and cluster dip (60 ppm available lodine)

Dilute one part product with 400 parts water (25 ml per 10 litres or 0.4 fl oz per gal) To help prevent cross infection, individual cloths or disposable paper towels are strongly recommended. Immerse clusters and agitate for at least half a minute. Rinse in clean water before use. Wash and dry udders and teats before milking

11. ADVICE ON CORRECT ADMINISTRATION

For professional use only

PRECAUTIONS

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

OPERATOR WARNINGS:

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 this product.

Keep away from food, drink and animal feedstuffs

12. WITHDRAWAL PERIOD

Meat-zero days Milk-zero hours.

13. SPECIAL STORAGE PRECAUTIONS

Store in tightly closed original container. Do not store above 25°C. Store diluted product only in plastic or glass containers Prepare product dilutions daily Protect from frost. Protect from light. If contents freeze they must be thawed and thoroughly mixed before use.

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

2021

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

For animal treatment only
[Distribution category]
AVM-GSL
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)

- 21. MANUFACTURER'S BATCH NUMBER
- 22. OTHER INFORMATION

Vm 03940/4053

Approved: 05/03/21

