

**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 Extra 0.535% w/v ready-to-use teat dip and teat spray solution

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

Iodine, Glycerol and Sorbitol.

**4. PHARMACEUTICAL FORM**

Masocare Extra 0.535% w/v ready-to-use teat dip and teat spray solution  
AVAILABLE IODINE and 11.32% w/v GLYCEROL and 0.68% w/v SORBITOL. 0.5% w/v available Iodine when used undiluted as a teat dip or spray. 0.00625% w/v available Iodine when diluted 1:80 as udderwash or cluster dip.

UK Authorised Veterinary Medicine.  
Ready-to-use iodophor formulation.  
Effective aid in the control of mastitis  
High emollient content (12%) to help maintain good teat condition.

Application Post-milking teat dip/spray  
Key ingredients Iodine, 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 or iodine adhering to teats which been treated by dipping or spraying.

Contains 11.32% w/v Glycerol and 0.68% w/v Sorbitol to help keep teats soft and supple all year round, and to aid in the prevention and healing of sores and cracks. Ready-to-use and so is especially suitable for situation where measurement and mixing are likely to prove inconvenient.

## **5. PACKAGE SIZE**

5,25,60,200 and 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 dipping

Fill teat cup about two-thirds full with the product. 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 product.

## Udder washing and cluster dipping

Dilute in the proportion of 1 part to 80 parts of clean water (125 ml per 10 litres or 2 fl oz per gal). Dry teats before milking. 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.

## **11. ADVICE ON CORRECT ADMINISTRATION**

For professional use only

Avoid contact with eyes. If splashed in eyes give prolonged irrigation with clean running water and seek medical advice. In case of ingestion seek medical advice immediately. When using as a spray, avoid working in spray mist. Do not eat, drink or smoke. Wash hands after use. Keep away animal feedstuffs.

## **12. WITHDRAWAL PERIOD**

Meat-zero days Milk-zero hours.

## **13. SPECIAL STORAGE PRECAUTIONS**

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

2016

**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
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**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>

03940/4085

**21. MANUFACTURER’S BATCH NUMBER**

**<22. OTHER INFORMATION>**

**Approved: 09/10/2017**

