

**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

PR5 8AH

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Masodip Extra 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution

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

Chlorhexidine Gluconate

benzalkonium Chloride

Glycerol and Sorbitol

**4. PHARMACEUTICAL FORM**

Ready To use Teat Dip and Teat Spray Solution

0.436% w/v Chlorhexidine formulation

0.01% w/v Benzalkonium Chloride

10.80% w/v Glycerol and 1.20% Sorbitol

**PRODUCT INFORMATION**

Based on Chlorhexidine formulation and Benzalkonium Chloride which work together to reduce the bacterial contamination that causes mastitis in dairy herds.

When used routinely as a teat dip or spray, it will prove a valuable aid in helping control Bovine mastitis.

Contains 10.80% w/v Glycerol and 1.2% Sorbitol to help prevent and heal cracked and chapped teats and to keep them soft and supple.

Ready to use and so is especially suitable for situations where measurements and mixing are likely to prove inconvenient.

## **5. PACKAGE SIZE**

1000,200.25 and 5

Additional wording to be added to 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.

Additional wording to be added to 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**

## **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.

Teat dip cups should be emptied and washed after use. **Teat Spraying**

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

### **Udder Washing and Cluster Dipping**

Dilute in the proportion of 150ml to 10 litres of clean water. 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**

When using as a spray, avoid working in spray mist

Avoid contact with eyes. In case of contact with eyes, give prolonged irrigation with water and seek medical advice

In case of ingestion seek medical advice immediately.

Do not eat, drink or smoke whilst using this product

Keep away from food, drink and animal feeding stuffs.

Wash hands after use.

### **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.

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. Rinse container thoroughly with water. Dispose of rinsing's in slurry or dirty water. Dispose of rinsed container in the farm refuse. Used containers should not be recycled.

**17. DATE ON WHICH THE LABEL WAS LAST APPROVED**

July 2016

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

For animal treatments only.

*[Distribution category]*

**19.     AVM-GSL 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> 03940/4055

**21. MANUFACTURER'S BATCH NUMBER**

**<22. OTHER INFORMATION>**

Approved: 24/07/2017

