

**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  
Brieley Road  
Walton Summit  
Preston  
Lancashire  
PR5 8AH

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

Golden 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**

Golden 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution contains and 5.35 mg/ml AVAILABLE IODINE and also contains 113.2 mg/ml GLYCEROL and 6.8 mg/ml SORBITOL.

Iodophor formulation.

Effective aid in the control of mastitis in dairy cows

113.2 mg/ml Glycerol and 6.8 mg/ml Sorbitol to help maintain good teat condition.

Dilute 1:80 in water as an Udder Wash.

Product information

Golden 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution is an iodophor-based solution which has been specially formulated to help reduce the bacterial contamination that causes mastitis in dairy herds.

Golden 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution reduces the risk of infection by leaving an antiseptic film or iodine adhering to teats which been treated by dipping or spraying.

Golden 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution contains 113.2 mg/ml Glycerol and 6.8 mg/ml Sorbitol.to help keep teats soft and supple all year round, and to aid in the prevention and healing of sores and cracks.

Golden 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution is ready to use and so 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 undiluted product. and dip the teats immediately after each has been milked. Top up the cup with dip if necessary. Teat dip cups should be emptied and washed before re-use.

### **TEAT SPRAYING**

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

### **UDDER WASHING AND CLUSTER DIPPING**

Use in the proportion of 1 part dip to 80 parts of water, i.e. 125 mls in 10 litres or 2 fl oz in 1 gallon. Udder cloths should be allowed to soak in the solution. The use of separate udder cloths for each cow, or disposable paper towels are strongly recommended. Teat clusters should be immersed and agitated for at least 30 seconds. Rinse in clean water before use. Wash and dry udder and teats before next milking.

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

For animal treatment only. For external use only. Keep out of the reach of children. Avoid contact with eyes. If sprayed/splashed in the rinse with clean running water and seek medical advice. In case of ingestion seek medical advice immediately. When used as a spray, avoid working in spray mist. When using do not eat, drink or smoke. Wash hands after use. Keep away animal feedstuffs.

#### **12. WITHDRAWAL PERIOD**

Meat and Offal-zero days Milk-zero hours.

#### **13. SPECIAL STORAGE PRECAUTIONS**

Store in the 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 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. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. To dispose of unused product to land you must have an authorisation under the Groundwater Regulations 2009.

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

June 2015

#### **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 reach of children.

**20. MARKETING AUTHORISATION NUMBER(S)**

Vm <number>

03940/4099

**21. MANUFACTURER’S BATCH NUMBER**

<22. OTHER INFORMATION>

**Approved: 09/10/2017**

