

**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**

Countdown 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**

Countdown Extra 0.535% w/v ready to use teat dip and teat spray solution  
Contains 0.535% w/v available Iodine and also contains 11.32% w/v Glycerol and 0.68% w/v Sorbitol. 5,000 ppm available Iodine minimum when used undiluted as a teat dip or spray. 62.5 ppm available Iodine minimum when diluted 1:80 as an udderwash or cluster dip.

Highly Effective Mastitis control.

Maintains superb teat condition – year round.

Iodophor Formulation – with 11.32% w/v Glycerol and 0.68 w/v Sorbitol.

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 12% w/v Glycerol and 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 Countdown Extra 0.535% w/v ready to use teat dip and teat spray 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 Countdown Extra 0.535% w/v ready-to-use teat dip and teat spray solution.

#### Udder washing and cluster dipping

Dilute in the proportion of 1 part to 80 parts of clean water (2 fl.oz. per gallon or 125 ml per 10 litre). 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**

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 container or label. Hands and exposed skin should be washed after using the product. Do not eat, drink or smoke whilst using the product. Keep away from food, drink and animal feedstuffs.

### **12. WITHDRAWAL PERIOD**

Meat-zero days Milk-zero hours.

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

Store in original container tightly closed 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 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 & 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**

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 the reach of children.

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

Vm <number>

03940/4097

**21. MANUFACTURER'S BATCH NUMBER**

**<22. OTHER INFORMATION>**

**Approved: 09/10/2017**

