

**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**

LEYODIP 2.15% w/v CONCENTRATE TEAT DIP and TEAT SPRAY SOLUTION.

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

Contains 2.15% w/v available iodine and 2% w/v glycerol and 18% w/v sorbitol.

**4. PHARMACEUTICAL FORM**

LEYODIP 2.15% w/v concentrate teat dip and teat spray solution is a controlled iodine concentrate teat dip in the form of a dark brown liquid.

**5. PACKAGE SIZE**

5,25,60,200

Additional wording required on 200 litre label:

200 litre label: This container should only be used once and should not be returned for re-filling.

**6. INDICATION(S)**

LEYODIP 2.15% w/v concentrate teat dip and teat spray solution should be used routinely, at the recommended dilute rates, as a teat dip, teat spray, udder wash and milking machine cluster dip, as part of a programme to control bovine mastitis and as an aid in the prevention and healing of cracked and chapped teats.

**1. CONTRAINDICATIONS**

None identified.

## 2. ADVERSE REACTIONS

None.

## 3. TARGET SPECIES

Dairy cows.

## 4. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

### TEAT DIPPING:

Prepare a fresh solution of 1 part LEYODIP 2.15% w/v CONCENTRATE TEAT DIP and TEAT SPRAY SOLUTION with three parts water, to give 5000ppm minimum available iodine. Fill teat dipping cup about two-thirds full with this prepared solution and dip each teat immediately after each cow is milked. Top up the cup with fresh solution if necessary. Teat dip cups should be emptied and washed after milking.

### TEAT SPRAYING:

Prepare a fresh solution of 1 part LEYODIP 2.15% w/v CONCENTRATE TEAT DIP and TEAT SPRAY SOLUTION with three parts water. Immediately after milking spray entire surface of each teat of every cow with the solution.

### UDDER WASHING and CLUSTER DIPPING:

Use in the proportion of 1 part LEYODIP 2.15% w/v CONCENTRATE TEAT DIP and TEAT SPRAY SOLUTION to 500 parts water, i.e. 20 ml in 10 litres or 1 fl oz in 3 gallons, to give 40ppm available iodine.

Udder cloths should be allowed to soak in the solution. The use of separate udder cloths for each cow, or disposable paper towels is strongly recommended.

Teat clusters should be immersed and agitated for at least 30 seconds before milking each cow.

## 11. ADVICE ON CORRECT ADMINISTRATION

### 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 container or label.

Hands and exposed skin should be washed after using this product.

Do not eat, drink or smoke while using the product.

Keep away from food, drink and animal feedstuffs.

## 12. WITHDRAWAL PERIOD

Milk: Zero hours.

Meat: Zero days.

**13. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.  
Store in tightly closed original container.  
Protect from frost.  
Diluted product should not be stored above 25°C.  
Protect from light.  
Once diluted use the product within 3 months.  
Store diluted product only in glass or plastic containers.

**14. SPECIAL WARNING(S)**

For animal treatment only. For external use only.  
Wash and dry udders and teats before next milking.

Keep out of reach of children.  
Keep away from animal feed.  
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**

September 2009

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

For animal treatment only.

*[Distribution category]*

**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>

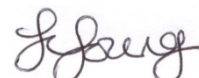
Vm03940/4094

**21. MANUFACTURER'S BATCH NUMBER**

**22. OTHER INFORMATION>**

**Further details are available from our representative**

**Approved: 09/10/2017**

A handwritten signature in black ink, appearing to read 'J. Long', is written below the approval date.