

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

COUNTDOWN1:4 2.72% W/V CONCENTRATE FOR TEAT DIP AND SPRAY SOLUTION

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

Iodine, Glycerol and Sorbitol.

4. PHARMACEUTICAL FORM

The product contains as active ingredient 2.72% w/v available iodine and also contains 42.5% w/v glycerol & 2.5% w/v sorbitol. 5,000ppm minimum available iodine when diluted 1:4 as a teat dip or spray. 62.5ppm available iodine when diluted 1:400 as udderwash or cluster dip. 9% emollient when diluted 1:4 as a teat dip or spray.

Concentrated teat dip.

Contains 42.50% w/v Glycerol & Sorbitol.

Contains Nonionic Surfactant.

Product information

COUNTDOWN1:4 2.72% w/v CONCENTRATE FOR TEAT DIP AND SPRAY SOLUTION is 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 of iodine adhering to teats which been treated by dipping or spraying. Contains glycerol and sorbitol solution to help keep teats soft and supple all year round, and to aid in the prevention and healing of sores and cracks.

5. PACKAGE SIZE

5,20,25,60 and 200 litres.

Additional wording required on 200 litre labels:

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: Prepare a fresh solution daily by adding 1 part product to 4 parts clean water. Fill teat dipping cup about two-thirds full with the solution and dip the teats of every cow immediately after milking, ensure the full length of the teat is covered. Top up cup with fresh solution as required. Teat dip cups should be emptied and washed after milking.

TEAT SPRAYING: Prepare a fresh solution daily by adding 1 part product to 4 parts clean water. Immediately after milking, spray entire surface of each teat of every cow with the solution.

UDDER WASHING & CLUSTER DIPPING: use in proportion of 1 part
COUNTDOWN 1:4 2.72%W/V CONCENTRATE TEAT DIP & TEAT SPRAY

SOLUTION added to 400 parts of water i.e. 0.4 fl oz per gallon or 25 ml per 10 litre. To prevent cross infection, individual cloths or disposable paper towels are strongly recommended. Dry teats before milking. Immerse clusters and agitate for at least half a minute. Rinse in clean water before use

11. ADVICE ON CORRECT ADMINISTRATION

PRECAUTIONS

For animal use only. For external use only. **OPERATOR WARNINGS:**

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 label.

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

Do not eat drink or smoke while using this product.

Keep away from food, drink and animal feedstuffs

Keep out of reach of children

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. Store diluted product only in plastic or glass containers Prepare product preparation daily Protect from frost. Protect from light. If contents freeze they must be thawed and thoroughly mixed before use.

14. SPECIAL WARNING(S)<User Warnings>

For animal use 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 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

2009

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

For animal use only

[Distribution category]

AVM-
GSL

19. THE WORDS “KEEP OUT OF THE SIGHT OF CHILDREN”

AND REACH OF

Keep out of reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

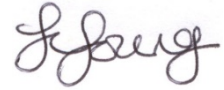
Vm <number>

03940/4063

21. MANUFACTURER’S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 09/10/2017

A handwritten signature in purple ink, appearing to read 'J. J. J.', is positioned below the approval date.