AN: 00287/2017

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

ACTION SUPER CONCENTRATE 1:3 TEAT DIP AND TEAT SPRAY SOLUTION 2.15% w/v.

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

lodine, Glycerol and Sorbitol.

4. PHARMACEUTICAL FORM

Concentrate for teat dip/spray solution.

Action Super Concentrate 1:3 Teat Dip and Teat Spray Solution 2.15% w/v contains 2.15% w/v available iodine, 2% w/v glycerol and 18% w/v sorbitol.

Diluted 1:3 as a teat dip or spray – 5000 ppm available iodine minimum.

Diluted 1:500 as an udderwash or cluster dip – 40 ppm available iodine minimum.

A concentrated iodine teat dip with glycerol and sorbitol.

PRODUCT INFORMATION

An iodine based teat dip and spray 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 that have been treated.

Contains glycerol and sorbitol to help keep teats soft and supple and aid in the prevention and healing of cracked and chapped teats.

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.

AN: 00287/2017

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

Dilute 1 part with 3 parts clean water. 5000ppm available iodine minimum. Fill teat dipping cup two-thirds full with the 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

Dilute 1 part with 3 parts clean water. 5000ppm available iodine minimum. Immediately after milking, spray entire surface of each teat of every cow with the solution.

Udder Washing

Dilute 1 part with 500 parts clean water. 40ppm available iodine minimum.

Change solution at regular intervals and whenever it becomes soiled

Wash teats of each cow with individual cloth/towel

Dry teats with individual paper towels before milking.

Cluster Dipping

Dilute 1 part to 500 parts clean water. 40ppm available iodine minimum.

Immerse clusters and agitate for at least half a minute.

Rinse in clean water before use.

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 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

AN: 00287/2017

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)<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. 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] | | | | |
|---|--|--|--|---------|
| | | | | AVM-GSL |
| | | | | |
| 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></number> | | | | |

Vm03940/4068

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION

AN: 00287/2017

Approved: 09/10/2017