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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

VENTURE IO-CARE 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution

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

lodine, Glycerol and Sorbitol.

4. PHARMACEUTICAL FORM

VENTURE IO-CARE 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution Ready To Use Iodophor Teat Dip/Spray.

Contains 0.535% w/v AVAILABLE IODINE and also contains11.32% w/v GLYCEROL and 0.68% w/v SORBITOL. 5,000 ppm available lodine minimum when used undiluted as a teat dip or spray.62.5 ppm available lodine minimum when diluted 1:80 as an udderwash or cluster dip.

Ready to use Iodophor formulation for dipping or spraying Contains 11.32% w/v Glycerol and 0.68 w/v Sorbitol. An effective aid in the prevention of Mastitis Made in UK

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.

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Contains 11.32% w/v Glycerol and 0.68% w/v Sorbitol Solution to help prevent heal cracked and chapped teats and to keep them soft and supple.

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

Instructions For Use

Wash and dry udders and teats before milking.

TEAT DIPPING

Fill teat dip cup about two thirds full with VENTURE IO-CARE 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution.

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Directly after milking each cow, dip each teat ensuring that the full length of the teat is immersed. No dilution is required. Replenish dip cup as necessary. Teat dip cups should be emptied after milking and washed before re-use.

TEAT SPRAYING

Directly after milking spray the entire surface of each teat with VENTURE IO-CARE 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution. No dilution is required.

UDDER WASHING & CLUSTER DIPPING

Dilute VENTURE IO-CARE 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution in the proportion of 1 part to 80 parts of clean water (125 ml per 10 litre).

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. Dry teats before milking.

11. ADVICE ON CORRECT ADMINISTRATION

Operator warnings: 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 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 tightly closed 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 external use only. For animal treatment only. Keep out of reach of children. If signs of disease persist or appear, consult your veterinary surgeon. Not for use on teats with broken skin.

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

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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

2012

<22. OTHER INFORMATION>

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

For animal treatment only	
[Distribution category]	
19. AVM-GSL	THE WORDS CHILDREN"
Keep out of the reach of children.	
20. MARKETING AUTHORISATION NUMBER(S)	
Vm <number></number>	
03940/4067	
21. MANUFACTURER'S BATCH NUMBER	

Approved: 09/10/2017