

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 321 CONCENTRATE TEAT DIP AND TEAT SPRAY SOLUTION 2.15% w/v.

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

2.15% available iodine
18% w/v sorbitol
2% w/v glycerol

5,000 ppm available iodine minimum when diluted 1:3 as a teat dip or spray
40 ppm available iodine minimum when diluted 1:500 as udderwash or cluster dip

4. PHARMACEUTICAL FORM

Concentrate for teat dip/spray solution.

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)

Venture 321 Concentrate Teat Dip and Teat Spray Solution 2.15% w/v is an iodophor-based teat dip and teat spray which has been specially formulated to help reduce the bacterial contamination that causes mastitis in dairy herds. Venture 321 Concentrate Teat Dip and Teat Spray Solution 2.15% w/v reduces the risk of infection by leaving an antiseptic film of iodine adhering to teats which have been treated by dipping or spraying. Venture 321 Concentrate Teat Dip and Teat Spray Solution 2.15% w/v contains 2% w/v glycerol and

18% w/v sorbitol 0.5% w/v glycerol and 4.5% w/v sorbitol when diluted) to help keep teats soft and supple, and to aid prevention and healing of sores and cracks.

1. CONTRAINDICATIONS

None identified.

2. ADVERSE REACTIONS

None.

3. TARGET SPECIES

Dairy cows.

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

Wash and dry udder and teats before milking.

Prepare a solution by diluting 1 part Venture 321 Concentrate Teat Dip and Teat Spray Solution 2.15% w/v with 3 parts clean water and mix well.

TEAT DIPPING 5,000ppm available iodine minimum when diluted 1:3 as a teat dip or spray.

Fill teat dipping cup two-thirds full with the prepared 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 entire surface of each teat of every cow with the solution.

UDDER WASHING AND CLUSTER DIPPING 40ppm minimum available iodine minimum when diluted 1:500 as udderwash or cluster dip.

Prepare a solution by diluting 1 part Venture 321 Concentrate Teat Dip and Teat Spray Solution 2.15% w/v with 500 parts clean water and mix well.

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

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. Keep out of reach and sight of children.
Not for use on broken skin.
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

January 2012

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)

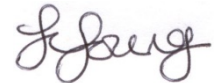
Vm <number>

Vm03940/4082

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION>

Approved: 09/10/2017

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