

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

Action Actodip Supreme 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution

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

Iodine, Glycerol and Sorbitol.

4. PHARMACEUTICAL FORM

ACTION ACTODIP SUPREME 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution contains 0.535% w/v available iodine and 9.0% w/v glycerol and 1.0% w/v sorbitol. undiluted as a teat dip or spray- 5000 ppm (minimum) available Iodine Dilute 1:80 as an udderwash or cluster dip – 62.5 ppm (minimum) available iodine.

Product information

ACTION ACTODIP SUPREME 0.535% w/v READY TO USE TEAT DIP AND TEAT SPRAY SOLUTION

A ready-to-use iodine teat care product suitable for use throughout the year giving exceptional teat skin condition

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. For full activity, allow cows to stand for 20 minutes after dipping.

Contains glycerol and sorbitol to help keep teats soft and supple all year round, and to aid in the prevention and healing cracked and chapped teats.

Supplied in ready to use form, no dilution or mixing required.

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

TEAT DIPPING

Fill teat dipping cup two-thirds full with Action Actodip Supreme 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution. Dip teats of every cow immediately after each one 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 teat dipping cups after milking.

TEAT SPRAYING

Immediately after milking, spray the entire surface of each teat of every cow with Action Actodip Supreme 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution

UDDER WASHING

Use a solution containing 1 part Action Actodip Supreme 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution to 80 parts clean water to wash teats and udders before milking. Use, individual cloths/towels, to reduce the risk of cross infection. Dry teats before milking.

CLUSTER DIPPING

Dilute 1 part to 80 parts clean water. Immerse clusters and agitate for at least half a minute. Rinse in clean water before use.

11. ADVICE ON CORRECT ADMINISTRATION

FOR EXTERNAL USE ONLY

For animal treatment only.

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. Keep out of reach of children. Wash and dry udders and teats before milking. Not for use on teats with broken skin.

12. WITHDRAWAL PERIOD

Meat-zero days Milk-zero hours.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C, store in tightly closed original container. Protect from frost. If contents freeze they must be thawed and thoroughly mixed before use.

14. SPECIAL WARNING(S)<User Warnings>

For animal treatment 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

2008

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

For animal treatment only

[Distribution category]

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

Keep out of reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

03940/4019

21. MANUFACTURER’S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 09/10/2017

