

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

Hexodip Extra 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution

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

Chlorhexidine Gluconate

benzalkonium Chloride

Glycerol and Sorbitol

4. PHARMACEUTICAL FORM

Ready To use Teat Dip and Teat Spray Solution

0.436% w/v Chlorhexidine formulation

0.01% w/v Benzalkonium Chloride

10.80% w/v Glycerol and 1.20% Sorbitol

PRODUCT INFORMATION

A Chlorhexidine ready to use high emollient teat dip and teat spray for use as an aid in the control of bovine mastitis.

Contains 0.46% w/v. Chlorhexidine Gluconate. Also contains 0.01% w/v Benzalkonium Chloride and 10.80% w/v Glycerol and 1.20% w/v Sorbitol.

5. PACKAGE SIZE

1000,200.25 and 5

Additional wording to be added to 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 use.

Additional wording to be added to 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

Wash and dry udders and teats before milking.

Teat Dipping

Fill teat cup about two thirds full with Hexodip Extra 0.436% w/v Ready to use teat dip and teat spray solution. No dilution is required.

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.

Teat dip cups should be emptied and washed after use.

Teat Spraying

Immediately after milking, spray the entire surface of each teat of every cow with Hexodip Extra 0.436% w/v Ready to use teat dip and teat spray solution.

Udder Washing and Cluster Dipping

Dilute in the proportion of 150ml Hexodip Extra 0.436% w/v Ready to use teat dip and teat spray solution to 10 litres of water. 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

For animal treatment only. For external use only.

Avoid contact with eyes. If sprayed/splashed in the eye rinse with clean running water and seek medical advice.

In case of ingestion seek medical advice immediately

When using as a spray, avoid working in spray mist.

Do not eat, drink or smoke. Whilst using this product.

Keep away from food, drink and animal feeding stuffs.

Wash hands after use.

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 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 regulation 1998.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

February 2009

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

For animal treatments only.

[Distribution category]

19. AVM-GSL THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm <number> 03940/4083

21. MANUFACTURER'S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 09/10/2017

