

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

Megorex 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

Megorex 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution formulation is based on Chlorhexidine Gluconate and Benzalkonium Chloride which work together to reduce the bacterial contamination that causes mastitis in dairy herds.

When used routinely as a teat dip or spray, Megorex 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution will prove a valuable aid in helping control Bovine mastitis.

Megorex 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution contains 10.80% w/v Glycerol and 1.20% Sorbitol to help prevent and heal cracked and chapped teats and to keep them soft and supple.

Megorex 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution is ready to use and so is especially suitable for situations where measurements and mixing are likely to prove inconvenient. No dilution required.

5. PACKAGE SIZE

200,25 and 5

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

Teat Dipping

Fill teat cup about two thirds full with Megorex 0.436% w/v Ready To Use Teat Dip and Teat Spray 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. 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 Megorex 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution.

Udder Washing and Cluster Dipping

Dilute in the proportion of 150ml to 10 litres of clean 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. Wash and dry udders and teats before milking.

11. ADVICE ON CORRECT ADMINISTRATION

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

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

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

In case of ingestion seek medical advice immediately.

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> 03940/4065

21. MANUFACTURER'S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 10/10/2017

