

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Super Concentrated Teat Dip, 2.12% w/v, Teat Dip Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Substance: 2.12% w/v minimum available Iodine

Other Constituents:

7.5% w/v Glycerol

7.5% w/v Sorbitol Solution 70% (Non- crystallising)

3. PHARMACEUTICAL FORM

Teat dip solution

4. PACKAGE SIZE

5 litres

10 litres

20 litres

25 litres

200 litres

5. TARGET SPECIES

Lactating dairy cattle

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]

As an aid in the prevention of mastitis in lactating dairy cattle. After each milking the diluted product is applied directly to the teats by spraying or by teat dipping with a teat cup.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Teat Dipping: Prepare a solution of 1 part teat dip with 3 parts water to give 5000 ppm available iodine. Fill teat-dipping cup approximately $\frac{2}{3}$ full with this solution and dip the teats immediately after each cow is milked. Top up the cup with fresh solution if necessary. Discard soiled solution. Prepare a fresh teat dip solution daily.

Udder Washing And Cluster Dipping: Use in the proportion of 1 part teat dip with 325 parts water (30ml in 10 litres) to give 62 ppm available iodine. Udder cloths should be allowed to soak in the solution. The use of separate udder cloths for each cow, or disposable paper towels is strongly recommended. Teat clusters should be immersed and agitated for at least 30 seconds before milking each cow. Prepare a fresh teat dip solution daily.

Teat Spraying: Prepare a solution of 1 part teat dip with 3 parts water. Immediately after each milking spray teats with this solution, covering the whole of the surface of the teat. Prepare a fresh teat dip solution daily.

8. WITHDRAWAL PERIOD

Meat – zero days / Milk – zero hours

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

CONCENTRATE

The following safety phrases refer 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.

Keep away from food, drink and animal feedstuffs.

Do not eat, drink or smoke whilst using the product

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

For one milking only when transferred to teat dip cup.

Use diluted product immediately. Discard any remaining diluted solutions at the end of each day.

Do not store above 25°C.

Protect from frost.

If the contents freeze it is important that they are thoroughly thawed and mixed before use.

Protect from direct sunlight.

Store upright, tightly closed in original container.

Store away from animal feed

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product should be disposed of in accordance with national requirements. To dispose of unused product to land, you must have an authorisation under the Groundwater Regulations 1998. Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

AVM- GSL

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kilco [International] Ltd.

Broomhouses 2 Industrial Estate

Old Glasgow Road

Lockerbie

Dumfriesshire

DG11 2SD

16. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

21357/4011

17. MANUFACTURER'S BATCH NUMBER

BN:

No Approved Packaging

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

Kilco [International] Ltd.

Broomhouses 2 Industrial Estate

Old Glasgow Road

Lockerbie

Dumfriesshire

DG11 2SD

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Other Constituents:

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4. PHARMACEUTICAL FORM

Teat dip solution

5. PACKAGE SIZE

5 litres

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7. CONTRAINDICATIONS

None

8. ADVERSE REACTIONS

None noted

9. TARGET SPECIES

Lactating dairy cattle

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

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Teat Spraying: Prepare a solution of 1 part teat dip with 3 parts water. Immediately after each milking spray teats with this solution, covering the whole of the surface of the teat. Prepare a fresh teat dip solution daily.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat – zero days / Milk – zero hours

13. SPECIAL STORAGE PRECAUTIONS

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Store upright, tightly closed in original container.

Store away from animal feed

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

14. SPECIAL WARNING(S)<User Warnings>

CONCENTRATE

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DILUTED WORKING SOLUTION

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Keep away from food, drink and animal feedstuffs.

Do not eat, drink or smoke whilst using the product

15. EXPIRY DATE

Exp:

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product should be disposed of in accordance with national requirements. To dispose of unused product to land, you must have an authorisation under the Groundwater Regulations 1998. Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included.]

<Find more product information by searching for the Product Information Database 'PID' on www.gov.uk.>

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

[Distribution category]

AVM- GSL

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

20. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

21357/4011

21. MANUFACTURER'S BATCH NUMBER

BN:

<22. OTHER INFORMATION>

Approved: 30/01/2018

