

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ready-to-Use Teat Dip/Teat Spray Solution, 0.538% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Substance: 0.538% w/v minimum available Iodine

Other Constituents: 2% w/v Glycerol

3. PHARMACEUTICAL FORM

Teat dip/spray solution

4. PACKAGE SIZE

5 Litres

10 Litres

20 Litres

25 Litres

200Litres

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 product is applied directly to the teats by spraying or teat dipping with a teat cup.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Teat Dipping: Ready to use, no dilution necessary. The solution should be used direct from the container without dilution. Fill teat dipping cup approximately 2/3rds full and immediately after each milking dip each teat in the solution, ensuring that the entire surface of the teat comes into contact with the solution. Top up the cup with fresh solution if necessary. Discard soiled solution.

Teat Spraying: Immediately after each milking spray the entire surface of the teats with the full strength solution.

Udder Washing And Cluster Dipping: Prepare a fresh solution daily. Use in the proportion of 1 part Product with 80 parts water. Udder cloths should be allowed to soak in the solution. The use of separate cloths for each cow, or disposable paper towels is strongly recommended.

Teat clusters should be immersed and agitated for at least 30 seconds in the solution before milking each cow.

Prepare fresh dilutions daily. Discard any remaining diluted solution at the end of the day.

8. WITHDRAWAL PERIOD

Meat – zero days / Milk – zero hours

9. SPECIAL WARNING(S), IF NECESSARY

<User 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.

Keep away from food, drink and animal feedstuffs.

Do not eat, drink or smoke while using the product.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Store upright, tightly closed in original container.

Store away from food, drink and animal feedstuffs.

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.

For one milking only when transferred to the teat dip cup.

Discard any remaining unused solutions at the end of each day

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

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. 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>

21357/4012

17. MANUFACTURER’S BATCH NUMBER

BN:

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

Ready-to-Use Teat Dip/Teat Spray Solution, 0.538% w/v

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

Active Substance: 0.538% w/v minimum available Iodine

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

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

Teat Dipping: Ready to use, no dilution necessary. The solution should be used direct from the container without dilution. Fill teat dipping cup approximately 2/3rds full and immediately after each milking dip each teat in the solution, ensuring that the entire surface of the teat comes into contact with the solution. Top up the cup with fresh solution if necessary. Discard soiled solution.

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Teat clusters should be immersed and agitated for at least 30 seconds in the solution before milking each cow.

Prepare fresh dilutions daily. Discard any remaining diluted solution at the end of the day.

11. ADVICE ON CORRECT ADMINISTRATION

For external use only. Teat dip cups should be emptied after each milking and washed thoroughly before re-use. Wash and dry udders and teats before next milking.

12. WITHDRAWAL PERIOD

Meat – zero days / Milk – zero hours

13. SPECIAL STORAGE PRECAUTIONS

Store upright, tightly closed in original container.

Store away from food, drink and animal feedstuffs.

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.

For one milking only when transferred to the teat dip cup.

Discard any remaining unused solutions at the end of each day

[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>

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 while using the product.

15. EXPIRY DATE

Exp:

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

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. 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>

21357/4012

21. MANUFACTURER'S BATCH NUMBER

BN:

<22. OTHER INFORMATION>

Approved: 30/01/2018

