

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

K Dip, 0.5% w/v, Teat Dip/Teat Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Substance:

Chlorhexidine gluconate solution 0.5%w/v

(added as 2.5% Chlorhexidine gluconate 20% solution)

Excipients:

Ponceau 4R (E124) 0.0016 % w/v

Other Constituents:

Glycerol 5.00% w/v

Sorbitol solution 70% (non-crystallising) 5.00% w/v

Ethoxylated lanolin 1.00% w/v

3. PHARMACEUTICAL FORM

Teat dip/spray solution

4. PACKAGE SIZE

5 Litres

10 Litres

20 Litres

25 Litres

200 Litres

1000 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 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: After milking dip the teats of each cow in the undiluted product ensuring the full length of the teat is covered.

Teat Spraying: After milking spray round the full surface of the teat including udders with the undiluted product.

8. WITHDRAWAL PERIOD

Meat – zero days / Milk – zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Special precautions to be taken by the person administering the medicinal product to animals.

When the product is used as a spray, avoid working in spray mist.

Avoid contact with eyes. In case of contact with eyes, give immediate prolonged irrigation with clean running water and seek medical attention.

In case of ingestion, seek medical attention immediately.

Do not eat, drink or smoke whilst using the product

Keep away from food, drink and animal feeding stuffs.

Wash hands after use.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed 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

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 21357/4014

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

K Dip, 0.5% w/v, Teat Dip/Teat Spray Solution

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

Active Substance:

Chlorhexidine gluconate solution 0.5%w/v

(added as 2.5% Chlorhexidine gluconate 20% solution)

Excipients:

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Other Constituents:

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4. PHARMACEUTICAL FORM

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5. PACKAGE SIZE

5 Litres

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[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 by 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: After milking dip the teats of each cow in the undiluted product ensuring the full length of the teat is covered.

Teat Spraying: After milking spray round the full surface of the teat including udders with the undiluted product.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat – zero days / Milk – zero hours

13. SPECIAL STORAGE PRECAUTIONS

Store in tightly closed 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.

14. SPECIAL WARNING(S)

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Wash hands after use.

15. EXPIRY DATE

Exp:

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

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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 21357/4014

21. MANUFACTURER'S BATCH NUMBER

<22. OTHER INFORMATION>

Use during pregnancy, and lactation or lay

The product is a medicinal disinfectant intended as an aid against mastitis. It is designed to be used on lactating dairy cattle and is applied externally without risk to the cow.

Do not mix with other products.

Approved: 30/01/2018

