

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EmpraSan Optima, 2.0 % w/v, Concentrate for Teat Dip / Teat Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Substance: 2.0% w/v minimum available Iodine

Other Constituents:

1.00% w/v Glycerol

2.00% w/v Ethoxylated Lanolin

3. PHARMACEUTICAL FORM

Concentrate for teat dip/spray solution

4. PACKAGE SIZE

5L, 10L, 25L, 200L

5. TARGET SPECIES

Lactating dairy cattle.

6. INDICATION(S)

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

The product is a concentrated teat dip which is diluted and then applied directly to the teats of dairy cattle by either semi-automatic hand held spray equipment or by dipping using a teat cup containing the product. Prepare fresh solution daily.

Pre milking teat dipping: If the teats are clean, dry wipe the teats with a paper towel. Use one disposable towel per cow. When the teats are dirty, clean with a paper towel soaked in udder wash ie: 25ml of product in 8 litres of clean water. Forestrip each teat. Prepare a solution of 1 part product added to 3 parts of clean water. Prepare a fresh solution daily. Fill the teat cup two thirds full with this solution. Dip each teat ensuring that the entire surface of the teat comes into contact with the solution. Allow a minimum contact time of 30 seconds. Refill the teat cup as

necessary from the solution. Teat cups should be emptied after use and washed before re-use.

Post-milking teat dipping / spraying: This concentrate requires to be diluted just prior to use.

Prepare a solution of 1 part product to 3 parts clean water. Prepare a fresh solution daily. Fill the teat cup two thirds full with this solution. After each cow has been milked, dip each teat ensuring that the entire surface of the teat comes into contact with the solution. Refill the teat cup as necessary from the solution. Teat cups should be emptied after use and washed before re-use. Wash and dry teats and udders before next milking. Dry teats thoroughly with a paper towel to remove iodine residues. Use one disposable towel for each cow.

Spraying: Prepare a solution of 1 part product to 3 parts clean water. Prepare a fresh solution daily. After each cow has been milked, spray the entire surface of each teat with the solution. Wash and dry teats and udders before next milking.

Udder washing: When the teats are dirty clean them with a paper towel soaked in 25 ml of product in 8 litres of clean water. When mastitis is in the herd use 25 ml of product in 4 litres of clean water. Prepare a fresh solution daily. Use one disposable paper towel for each cow.

Cluster dipping: Between transferring clusters from one cow to the next, plunge the clusters 3 times into a solution prepared by adding 25 ml of teat dip concentrate to 8 litres of water.

8. WITHDRAWAL PERIOD

Meat – zero days

Milk – zero hours

9. SPECIAL WARNING(S), IF NECESSARY

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.

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

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

Adverse reactions (frequency and seriousness)

None noted.

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.

Interaction with other medicinal products and other forms of interaction

Do not mix with other products.

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 veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

DG11 2SD

16. MARKETING AUTHORISATION NUMBER(S)

Vm 21357/4023

17. MANUFACTURER'S BATCH NUMBER

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

DG11 2SD

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EmpraSan Optima, 2.0 % w/v, Concentrate for Teat Dip / Teat Spray Solution

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

Active Substance: 2.0% w/v minimum available Iodine

Other Constituents:

1.00% w/v Glycerol

2.00% w/v Ethoxylated Lanolin

4. PHARMACEUTICAL FORM

Concentrate for teat dip/spray solution

5. PACKAGE SIZE

5L, 10L, 25L, 200L

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. CONTRAINDICATIONS

None

8. ADVERSE REACTIONS

None noted

9. TARGET SPECIES

Lactating dairy cattle

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

The product is a concentrated teat dip which is diluted and then applied directly to the teats of dairy cattle by either semi-automatic hand held spray equipment or by dipping using a teat cup containing the product. Prepare fresh solution daily.

Pre milking teat dipping: If the teats are clean, dry wipe the teats with a paper towel. Use one disposable towel per cow. When the teats are dirty, clean with a paper towel soaked in udder wash ie: 25ml of product in 8 litres of clean water. Forestrip each teat. Prepare a solution of 1 part product added to 3 parts of clean water. Prepare a fresh solution daily. Fill the teat cup two thirds full with this solution. Dip each teat ensuring that the entire surface of the teat comes into contact with the solution. Allow a minimum contact time of 30 seconds. Refill the teat cup as necessary from the solution. Teat cups should be emptied after use and washed before re-use.

Post-milking teat dipping / spraying: This concentrate requires to be diluted just prior to use.

Prepare a solution of 1 part product to 3 parts clean water. Prepare a fresh solution daily. Fill the teat cup two thirds full with this solution. After each cow has been milked, dip each teat ensuring that the entire surface of the teat comes into contact with the solution. Refill the teat cup as necessary from the solution. Teat cups should be emptied after use and washed before re-use. Wash and dry teats and udders before next milking. Dry teats thoroughly with a paper towel to remove iodine residues. Use one disposable towel for each cow.

Spraying: Prepare a solution of 1 part product to 3 parts clean water. Prepare a fresh solution daily. After each cow has been milked, spray the entire surface of each teat with the solution. Wash and dry teats and udders before next milking.

Udder washing: When the teats are dirty clean them with a paper towel soaked in 25 ml of product in 8 litres of clean water. When mastitis is in the herd use 25 ml of product in 4 litres of clean water. Prepare a fresh solution daily. Use one disposable paper towel for each cow.

Cluster dipping: Between transferring clusters from one cow to the next, plunge the clusters 3 times into a solution prepared by adding 25 ml of teat dip concentrate to 8 litres of water.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat – zero days

Milk – zero hours

13. SPECIAL STORAGE PRECAUTIONS

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

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

<When the container is breached/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

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.

15. EXPIRY DATE

Exp.

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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"

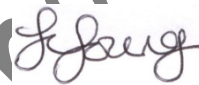
20. MARKETING AUTHORISATION NUMBER(S)

Vm 21357/4023

21. MANUFACTURER'S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 30/01/2018

A handwritten signature in dark ink, appearing to read 'J. J. J.', is written over the 'Approved' text.

No Approved Packaging