

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

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

EmpiraSan Sovereign, 2.82% w/v, Concentrate for Teat Dip / Teat Spray Solution

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Active Substance: 2.82% w/v minimum available Iodine

Other Constituents:

22.79% w/v Glycerol

3.8 %w/v Ethoxylated Lanolin

**3. PHARMACEUTICAL FORM**

Teat dip/spray solution

**4. PACKAGE SIZE**

5 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**

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.

Post-milking teat dipping / spraying: This concentrate requires to be diluted just prior to use. Prepare a solution of 1 part product to 4 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.

**Spraying:** Prepare a solution of 1 part product to 4 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 12 ml of product in 8 litres of clean water. When mastitis is in the herd use 12 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 12 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**

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

## **10. EXPIRY DATE**

Exp:

## 11. SPECIAL STORAGE CONDITIONS

For one milking only when transferred to teat dip cup.

Dilute immediately before use, any unused diluted product should be discarded.

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.

## 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
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## 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 21357/4022

**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

DG11 2SD

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

EmpraSan Sovereign, 2.82% w/v, Concentrate for Teat Dip / Teat Spray Solution

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

Active Substance: 2.82% w/v minimum available Iodine

Other Constituents:

22.79% w/v Glycerol

3.8 %w/v Ethoxylated Lanolin

**4. PHARMACEUTICAL FORM**

Teat dip/spray solution

**5. PACKAGE SIZE**

5 Litres

**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.

Post-milking teat dipping / spraying: This concentrate requires to be diluted just prior to use. Prepare a solution of 1 part product to 4 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.

Spraying: Prepare a solution of 1 part product to 4 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 12 ml of product in 8 litres of clean water. When mastitis is in the herd use 12 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 12 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.

Dilute immediately before use, any unused diluted product should be discarded.

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.

### **14. SPECIAL WARNING(S)<User Warnings>**

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**

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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](http://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 21357/4022

**21. MANUFACTURER'S BATCH NUMBER**

BN:

**<22. OTHER INFORMATION>**

Approved: 30/01/2018

