

SUMMARY OF PRODUCT CHARACTERISTICS

1) Name of the veterinary medicinal product

EmpraSan Extracare, 0.6% w/v, ready-to-use teat dip / teat spray solution

2) Qualitative and Quantitative composition

Active Substance: 0.6% w/v Iodine

Other Constituents:

10.05% w/v Glycerol

0.5% w/v Ethoxylated Lanolin

For full list of excipients see section 6.1

3) Pharmaceutical form

Teat dip/Teat Spray Solution

Description: Mobile brown liquid

4) Clinical particulars:

4.1 Target species.

Lactating dairy cattle.

4.2 Indications for use, specifying the target species.

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.

4.3 Contra-indications.

None

4.4 Special warnings for each target species.

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.

4.5 Special precautions for use

i) Special precautions for use in animals

None

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

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

4.6 Adverse reactions (frequency and seriousness).

None noted.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction.

Do not mix with other products.

4.9 Amounts to be administered and administration route.

The product is a ready-to-use teat dip which is 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: The product should be used direct from the container without dilution. Fill the teat cup two thirds full with the product. After each cow has been milked, dip each teat ensuring that the entire surface of the teat comes into contact with the product. Refill the teat cup as necessary. Teat cups should be emptied after use and washed before re-use. Wash and dry teats and udders before next milking.

Spraying: The product should be used direct from the container without dilution. After each cow has been milked, spray the entire surface of each teat with the product. Wash 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 2.5 litres of clean water. When mastitis is in the herd use 25 ml of product in 1.25 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 mls of teat dip concentrate to 2.5 litres of water Prepare a fresh solution daily.

4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary.

The limited external use of this product makes an overdose very unlikely.

4.11 Withdrawal period(s)

Meat – zero days / Milk – zero hours

5) Pharmacological properties

5.1 Pharmacodynamic properties.

Iodine is a halogen element being a member of Group VII of the Periodic Table. In common with other members of this group, notably chlorine, it is a broad-spectrum bactericide useful for skin disinfection. ATC Vet Code: QD08AG03

5.2 Pharmacokinetic particulars.

The product is for external use only.

6) Pharmaceutical particulars:

6.1 List of excipients.

Glycerol
Ethoxylated Lanolin
Alcohol 8 mole Ethoxylate
Sodium Acetate Trihydrate
Hydroiodic Acid
Water Potable

6.2 Incompatibilities.

Incompatible with Chlorhexidine-based teat dips.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale; 1 year.

6.4 Special precautions for storage.

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.

Store upright, tightly closed in original container.

Store away from animal feed

6.5 Nature and composition of immediate packaging.

Available in;

5 litre blue opaque high density polyethylene drum, closed with white high density polyethylene screw fit caps.

25 litre blue or white opaque high density polyethylene drum closed with white or black high density polyethylene screw fit caps.

200 or 1000* litre blue or black opaque high density polyethylene drums closed with high density polyethylene screw-fit bungs with internal thread.

*Ensure that all equipment and containers used for decanting not more than enough product for use that day, are fit for purpose, clean, emptied after use and washed before re-use.

Not all pack sizes may be marketed.

The 200 and 1000 litre containers should only be used once and should not be returned for re-filling.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate.

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

7) Marketing Authorisation holder.

Kilco [International] Ltd.
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DG11 2SD

8) Marketing authorisation number.

Vm 21357/4015

9) Date of the first authorisation.

12 March 2010

10) Date of revision of the text.

12 March 2010