SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

3TX 1:3 2.15% w/v Concentrate for Teat Dip and Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Available Iodine	21.5 mg/ml

For the full list of excipients see 6.1

3. PHARMACEUTICAL FORM

Concentrate for teat dip and teat spray solution.
Dark brown aqueous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dairy cows

4.2 Indications for use, specifying the target species

As an aid in the control of mastitis in lactating dairy cows, and as an aid in the prevention and healing of cracked and chapped teats.

4.3 Contraindications

None identified

4.4 Special warnings for each target species

For external use only. Not to be used in conjunction with any other teat dip product.

4.5 Special precautions for use

i. Special precautions for use in animals

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

ii. Special precautions for the person administering the veterinary medicinal product to animals

CONCENTRATE
The following safety phrases relate 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 label.
Hands and exposed skin should be washed after using this product.
Do not eat, drink or smoke while using the product.
Keep away from food, drink and animal feedstuffs.

4.6 Adverse reactions (frequency and seriousness)

The product may cause an allergic reaction in some animals. In the rare case of a suspected or proven allergy in the herd, it is recommended to change to a non-iodine teat disinfectant.

4.7 Use during pregnancy, lactation or lay

May be used during pregnancy and lactation

4.8 Interaction with other medicinal products and other forms of interaction

Not applicable

4.9 Amount(s) to be administered and administration route

Teat dipping
Mix 1 part of the product with three parts clean water. Fill teat-dipping cup about two thirds full with the solution and dip teats immediately after each cow is milked. Top up cup with fresh solution if necessary.

Teat Spraying
Mix 1 part of the product with three parts clean water. Immediately after milking, spray the entire surface of each teat with the solution.

Udder washing and cluster dipping
Use in the proportion 1 part product in 500 parts clean water i.e. 20ml in 10 litres or 1 fl. in 3 gallons. Udder cloths should be allowed to soak in the solution. The use of separate udder cloths for each cow, or disposable paper towels, is strongly recommended. Teat clusters should be immersed and agitated for at least 30 seconds before milking each cow. Rinse in clean water before use.

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

Not applicable

4.11 Withdrawal period(s)

Milk: Zero hours

Meat: Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, Antiseptics and Disinfectants, iodine

ATC Vet Code: QD08AG03

5.1 Pharmacodynamic properties

Iodine has a powerful bactericidal action. It is also active against fungi, viruses, protozoa, cysts and spores. Iodine is used as a disinfectant generally as a 2% or 2.5% solution. Its activity is reduced in the presence of organic matter, though not to the same extent as with other halogen disinfectants. A solution of iodine may be applied to small wounds or abrasions as well as to unbroken skin, but an iodophor such as povidone iodine may be preferred.

Iodine and iodides, whether applied topically or administered systemically, can also give rise to hypersensitivity reactions, which may include urticaria, angioedema, cutaneous haemorrhage or purpuras, fever, arthralgia, lymphadenopathy and eosinophilia

5.2 Pharmacokinetic properties

Iodine may be administered as potassium or sodium iodate.

Iodine is slightly absorbed when applied to the skin. When taken by mouth, iodine preparations (which are converted to iodide) and iodides are trapped by the thyroid gland. Solutions of iodine applied to the skin should not be covered by occlusive dressings.

Iodides not taken up by the thyroid are excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and sweat. They cross the placenta and are excreted in breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol ($C_{13}C_{15}$) 11 Mole Ethoxylate
Sorbitol
Glycerol
Sodium Hydroxide
Hydriodic Acid
Sodium Sulphate
Water Potable

6.2 Incompatibilities

Iodine based teat dips are not compatible with chlorhexidine based products, hypochlorite solutions and other oxidising agents and alkaline soaps and detergents

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after dilution or reconstitution according to directions: 3 months

6.4 Special precautions for storage

Do not store above 25°C.
Store in original tightly closed container.
Protect from frost.
Store diluted product only in plastic or glass containers.
Diluted product should not be stored above 25°C. Protect from light and use within 3 months.

6.5 Nature and composition of immediate packaging

*natural UN approved 1000 litre high density polyethylene
*Opaque Blue XL-200 litre ring drum with two inserted bungs 81mm & 69mm
*Opaque Blue 60 litre drum with one inserted bung
25 litre, white, natural or black high density polyethylene drum with high density polyethylene screw cap.(tamper evident)
*Opaque Pale Blue high density polyethylene 5 litre container polyethylene screw cap
*Other colours may be used i.e. white, grey, green or colourless

Not all pack sizes may be marketed
The 200 litre and 1000 litre containers should not be returned for re-filling

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 2009.
Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7 MARKETING AUTHORISATION HOLDER

Evans Vanodine International Plc
Brierley Road
Walton Summit
Preston
Lancashire
PR5 8AH

8. MARKETING AUTHORISATION NUMBER

Vm 03940/4098

9. DATE OF FIRST AUTHORISATION

08 May 2009

10. DATE OF REVISION OF THE TEXT

August 2016


05 August 2016