SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

1:3 Concentrate Teat Dip/Teat Spray Solution and Udder Wash 2.15%w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s)	% w/v
Iodine	2.15
Other Relevant Constituents	
Sorbitol	18.00
Glycerol	2.01

For a 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

Not to be used in conjunction with any other teat dip product.

4.5 Special precautions for use

For external use only.

i. Special precautions for use in animals

Not to be applied to teats with broken and damaged skin.

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 container or label.

Hands and exposed skin should be washed after using this product.

Do not eat drink or smoke while using this 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

None known.

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.oz. 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

ATC Vet Code: QD 08AG03

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.

5.2 Pharmacokinetic properties

Iodine is an essential trace element in the human diet, it is necessary for the formation of thyroid hormones. It is used for the prophylaxis and treatment of iodine deficiency disorders such as endemic goitre, in areas where the diet is deficient in iodine. It 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.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

1. Hypochlorite solution
2. Phenolic/Soap/Pine oil disinfectants
3. Chlorhexidine teat disinfectants
4. 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 container. Keep the container tightly closed.
Protect from frost.
Store diluted product only in plastic or glass containers.
Diluted product should not be stored above 25°C. Protect from light. Once diluted, use the product within 3 months.

6.5 Nature and composition of immediate packaging

*1000 litre Natural UN Approved high density polyethylene

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 use.

* 200 litre, 60 litre opaque, white, blue, grey, green, black or colourless high density polyethylene drum with polypropylene co-polymer bung (2 bungs on 200 litre).

25 litre, 5 litre opaque, white, blue, grey, green, black or colourless high density polyethylene drum with high density polyethylene screw fit cap

(tamper evident on 25 litres).

*The 200 litre and 1000 litre container should not be returned for re-filling.

Not all pack sizes may be marketed.

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 1998.
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
PR5 8AH
ENGLAND

8. MARKETING AUTHORISATION NUMBER(S)

Vm 03940/4074

9. DATE OF FIRST AUTHORISATION

Date: 2nd April 2001

10. DATE OF REVISION OF THE TEXT

Date: August 2011