## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actodip Supreme 2.72% w/v Concentrate for Teat Dip and Teat Spray Solution.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition

Active Substance
Iodine
(as F309A intermediate)

Other Relevant Constituents

Glycerol
Sorbitol

For a list of full 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

To be applied diluted by dipping or spraying to dairy cows' teats immediately after milking, 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

None known

## 4.5 Special precautions for use

**For external use only.**

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 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.
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iii. Other precautions

None.

## 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

The product is safe to use on pregnant and lactating cows.

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

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

## 4.9 Amount(s) to be administered and administration route

Teat dipping: Mix 1 part product with 4 parts of water. Fill teat dipping cup about two thirds full with the solution and dip the teats immediately after each cow is milked. Top up the cup with fresh solution if necessary.
Teat spraying: Mix 1 part product to 4 parts water. Immediately after milking, spray the entire surface of each teat with the solution. Prepare a fresh solution of the

diluted product daily before dipping or spraying. Teat dip cups should be emptied after milking and washed before re-use. Wash and dry udders and teats before next milking.
Udder Washing and cluster dipping: Mix 1 part product with 400 parts water.

### 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:**

**ATC Vet Code:**
QD 08AG03

### 5.1 Pharmacodynamic properties

Iodine has a powerful broad spectrum bactericidal action and is used for disinfecting unbroken skin before operation. It is also active against fungi, viruses, protozoa, cysts and spores. It is generally employed as a disinfectant for human skin application as a 2% or 2.5% solution of iodine . The germicidal activity is reduced in the presence of organic matter although the reduction is reported to be less than that observed with other halogen disinfectants.
Iodophors (such as the product) as teat disinfectants have a strong activity against a wide range of bacteria.

### 5.2 Pharmacokinetic properties

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

Distribution and Elimination:
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

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

### 6.2 Incompatibilities

1. Hypochlorite solutions and other oxidising agents
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.

### 6.4 Special precautions for storage

Do not store above 25°C.
Store in tightly closed original container.
Protect from frost.
Store diluted product only in plastic or glass containers.
Prepare product preparations daily.
If contents freeze they must be thawed and thoroughly mixed before use.
Protect from light.

### 6.5 Nature and composition of immediate packaging

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

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

25 litre white, natural or black high density polyethylene drum with high density polyethylene screw cap (tamper evident).

20 litre natural UN Eurostacker container with high density polyethylene tamper-evident, screw-fit cap.

*The 200 litre containers 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
Lancashire
PR5 8AH

## 8. MARKETING AUTHORISATION NUMBER

Vm 03940/4061

## 9. DATE OF FIRST AUTHORISATION

02 February 2000

## 10. DATE OF REVISION OF THE TEXT

**Date:** March 2016

Approved: 22 March 2016