1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Action Actodip Supreme 0.535% w/v Ready To Use Teat Dip and Teat Spray Solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active Substance(s)	**% w/v**
Iodine (as F309A intermediate)	0.535
Other Relevant Constituents	
Glycerol	9.000
Sorbitol	1.000

For full list of excipients see 6.1.

3. PHARMACEUTICAL FORM

Teat Dip/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 undiluted, 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.

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.

ii. Special precautions for the person administering the veterinary 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.
Do not eat drink or smoke while using the product.
Keep away from food, drink and animal feedstuffs.

iii Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Iodophor teat disinfectants can be regarded as safe for the dairy cow when used as recommended. At the concentrations used for post milking teat sanitation (5000 ppm) their local and resorptive tolerance is good. In the rare case of a suspected proven allergy in the herd, it is recommended to change to an 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 - Fill teat dipping cup about two thirds full and dip the teats immediately after each cow is milked. Top up the cup with dip if necessary. Teat dip cups should be emptied and washed before re-use.

Teat spraying - Immediately after milking, spray the entire surface of each teat with the solution.

Udder washing and cluster dipping - Use in the proportion of 1 part dip to 80 parts of water, i.e. 125 mls in 10 litres or 2 fl.oz. in 1 gallon. 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. Rinse in clean water before use.
Wash and dry udder and teats before next milking.

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:

QD08AG53

5.1 Pharmacodynamic properties

Iodine has a powerful 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 as teat disinfectants have a wide range of activity against mastitis causing bacteria.

5.2 Pharmacokinetic properties

Absorption:

When taken by mouth, iodine preparations (which are converted to iodide) and iodides are absorbed throughout the gastro-intestinal tract in man but mainly from the rumen in cattle. It accumulates in the thyroid gland and concentrates in gastric and salivary secretions. 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 are excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and 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

Store in tightly closed original container. Do not store above 25°C. Protect from frost. If contents freeze they must be thawed and thoroughly mixed before use.

6.5 Nature and composition of immediate packaging

Natural 1000* litre natural UN approved high density intermediate bulk container (IBC) with tap.
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 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).

*The 200 litre and 1000 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 03940/4019

9. DATE OF FIRST AUTHORISATION

6 Janurary1997

10. DATE OF REVISION OF THE TEXT

March 2016

Approved: 16 March 2016