

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suredip 0.74% w/v Teat dip/Teat spray, solution — ready to use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Chlorhexidine gluconate 0.74% w/v

Excipient:

Amaranth (E123) 0.001 % w/v

Other constituents:

Glycerol 10.30 % w/v

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Teat dip/Teat spray, solution
A pink clear or translucent liquid.

4. CLINICAL PARTICULARS

This product contains chlorhexidine gluconate as a biocide. The agent is a bactericidal disinfectant which belongs to the biguanidine group of cationic surfactants that act by disrupting cellular matter. The emollients aid in teat care and health.

4.1 Target species

Lactating dairy cows, sheep and goats

4.2 Indications for use, specifying the target species

When used as a teat dip / teat spray is an aid in the prevention of the spread of mastitis in lactating dairy cattle, sheep and goats.

4.3 Contraindications

None

4.4 Special warnings for each target species

For external use only.

4.5 Special precautions for use

i. Special precautions for use in animals

Wash and dry udders and teats before next milking. Empty teat dipping beakers after each milking and wash before reuse.

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

Avoid contact with eyes. If splashed in the eye, rinse with clean running water and seek medical advice.

In case of ingestion seek medical advice immediately.

When used as a spray, avoid working in a spray mist.

Keep away from animal feed.

Wash hands after use.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Skin sensitivity to Chlorhexidine is rare and no suspected adverse reactions have been reported so far.

4.7 Use during pregnancy, lactation or lay

Safe for use in pregnant and lactating cows, sheep and goats. The product is a medicinal disinfectant for external application as an aid against mastitis.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use in conjunction with any other treatment for disinfection of teats/udders — not compatible with iodine based teat dips. No practitioner has advocated that daily use of chlorhexidine based teat dips should cease when other medicinal measures are being taken.

4.9 Amount(s) to be administered and administration route

Ready to use preparation for the external application to the teats of lactating cows, sheep and goats.

Teat Dipping

Fill the dipping beakers two thirds (2/3) full and apply to the teats of the lactating cows, sheep or goats immediately after milking.

The dipping beakers should be emptied after each milking and washed before reuse. Replenish dipping beakers after each milking.

Teat Spraying

Immediately after the milking of cows, sheep or goats spray the entire surface of each teat.

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

Not applicable — external teat surface treatment only.

4.11 Withdrawal period(s)

Meat: Zero days and Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Products for teats and udder, Disinfectants

ATC Vet Code: QG52A

Veterinary Disinfectant: Dermatologicals:
Antiseptics and disinfectants: Chlorhexidine

5.1 Pharmacodynamic properties

The active ingredient is a disinfectant with bactericidal activity against most bacteria. The post milking topical application of the product to the teats of lactating cows, sheep and goats prevents the ingress of pathogenic organisms into the streak canal of the teat and thereby aids in the prevention of the spread of mastitis from infected quarters to non-infected quarters.

5.2 Pharmacokinetic properties

Work done by the Institute for Animal Health, Compton, Newbury, UK in 1991 demonstrates that post milking topical application of the product to the teats of lactating cows, resulted in the absorption into milk of a level of the active ingredient not exceeding 10 ppb.

6. PHARMACEUTICAL PARTICULARS

SUREDIP is a ready to use teat dip/spray containing chlorhexidine gluconate and emollients as an aid in the prevention of the spread of mastitis in lactating dairy cattle, sheep and goats.

6.1 List of excipients

Amaranth (E123)
Glycerol
Peg 75 Lanolin
Water deionised
Alcohol C9-11 6 mole Ethoxylate

6.2 Incompatibilities

Chlorhexidine gluconate is incompatible with soaps or washing up liquids or anionic surfactants. Do not mix with sodium hypochlorite solutions or alkaline mixtures.

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.
Protect from frost.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

25, 30 and 45 litres natural, high density polyethylene container with high density polyethylene cap (screw fit, tamper evident) with expanded polyethylene foam washer.

200 litres blue high density polyethylene drum with polypropylene bung (tamper evident).

The 200 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.

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

GEA FARM TECHNOLOGIES (UK) LTD
Wylle Works
Watery Lane
Bishopstrow
Warminster
Wiltshire
BA12 9HT

8. MARKETING AUTHORISATION NUMBER(S)

Vm 01808/4006

9. DATE OF FIRST AUTHORISATION

Date: 14 February 1985

10. DATE OF REVISION OF THE TEXT

Date: September 2012