

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexaguard 3.7% concentrate for teat dip or teat spray.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Chlorhexidine gluconate solution (20% Ph.Eur) to provide concentration of Chlorhexidine gluconate 3.70 % w/v.

Other constituents:

- Lanolin Compound
- Glycerol
- Alcohol 6 mole ethoxylate:3 mole propoxylate
- Ethylene oxide/propylene oxide block copolymer
- Patent blue V (dye – E131)
- Water deionised

3 PHARMACEUTICAL FORM

Concentrate for Teat Dip or Teat Spray solution.
Requires dilution before use.

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

Pregnant and lactating dairy cows, sheep and goats.

4.2 Indications for use, specifying the target species

When used as a teat dip/teat spray as 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.

If signs of disease persist or appear consult your veterinary surgeon.

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

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.

4.9 Amounts to be administered and administration route

Suredip Concentrate is a preparation that should be diluted prior to use.

Teat Dipping

Make up a stock solution daily by diluting 1 part of Suredip (Hexaguard) Concentrate with 4 parts of water. The stock solution will contain 7400 ppm chlorhexidine gluconate.

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

Make a stock solution daily by diluting 1 part of Suredip (Hexaguard) Concentrate to 4 parts of water. Immediately after the milking of cows, sheep and goats spray the entire surface of each teat. The stock solution will contain 7400 ppm chlorhexidine gluconate.

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

Not applicable – external teat surface treatment only.

4.11 Withdrawal Period(s)

Meat and Milk: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group

Veterinary Disinfectant: Dermatologicals

Antiseptics and disinfectants: Chlorhexidine

ATC Vet Code: QD08AC02

5.1 Pharmacodynamic properties

The active ingredient is a disinfectant with bactericidal activity against most bacteria. The post milking topical application of the (diluted) 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 (Hexaguard) Concentrate is a preparation that should be diluted prior to use which contains 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

Glycerol (CAS No. 56-81-5) , Water soluble Lanolin compound (CAS No. 61790-81-6) , Patent blue V (dye – E131), polymeric non-ionic surfactants : Alcohol 6 mole ethoxylate:3 mole propoxylate (CAS No. 68154-97-2) and Ethylene oxide/propylene oxide block copolymer (CAS No. 90003-11-6)

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.

Do not mix with iodine based teat dips.

6.3 Shelf-life

Two 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

Hexaguard concentrate is packed in

- 5 litre liquid teat dip in blow moulded high density polyethylene jerrican style containers complete with tamper evident screw cap.
- 20, 25 and 45 L liquid teat dip in a natural square/round high density polythene container with screw cap (tamper evident) closure.
- 200 L liquid teat dip in a cylindrical polyethylene container with combination bung.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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. Do not contaminate ponds or ditches with this product or used container.

7 MARKETING AUTHORISATION HOLDER

GEA Farm Technologies (UK) Ltd.,
Wylie Works,
Watery Lane,
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Warminster,
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8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10844/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31st July 2007

10 DATE OF REVISION OF THE TEXT

August 2012