

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexaguard.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Chlorhexidine gluconate 0.74% w/v
(as chlorhexidine digluconate solution Ph. Eur.)

Excipients

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat Dip. A pint clear or translucent liquid.

4 CLINICAL PARTICULARS

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 Hexaguard (Ready to use) teat dip is an aid to the prevention of mastitis in lactating dairy cows, sheep and goats.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

For external use only.

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 practitioner.

4.5 Special precautions for use

Special precautions for use in animals

For external use only.

Special precautions to be taken by the person administering the 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Hexaguard (Ready to use) Teat Dip is safe to use in pregnant and lactating cows, sheep and goats.

4.8 Interaction with other medicinal products and other forms of interaction

Not to be used in conjunction with any other medications.

Incompatible with iodine based teat dips.

4.9 Amounts to be administered and administration route

Hexaguard (Ready to use) Teat Dip is a ready-to-use preparation.

Teat Dipping

Fill the dipping beakers two thirds (2/3) full and apply to the teats of the lactating cows, sheep and 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 and goats spray the entire surface of each teat.

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

Not applicable.

4.11 Withdrawal Period(s)

Edible tissues and milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Therapeutic Group; Antiseptics and disinfectants.

ATC vet code; QD08AC02

The post milking application of Hexaguard (Ready to use) teat dip to the teats of lactating cows, sheep and goats significantly reduces the number of mastitic causing organisms on the external surfaces of teats. Hexaguard is a bactericidal disinfectant which contains the active agent chlorhexidine gluconate which belongs to the biguanidine group of cationic surfactants which act by disrupting cellular matter.

5.1 Pharmacodynamic properties

The post milking topical application of Hexaguard (Ready to use) teat dips 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 Hexaguard (ready to use) teat dips 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

6.1 List of excipients

Lanolin
Cetyl alcohol ethoxylate
Glycerol
Deionised water
Amaranth (E123)

6.2 Incompatibilities

None known.

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 L 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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

Harmful to fish. Do not contaminate ponds or ditches with this product or used containers.

7 MARKETING AUTHORISATION HOLDER

GEA Farm Technologies (UK) Ltd.,
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10844/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

May 2012