

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alfa Red Teat dip/Teat spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Chlorhexidine digluconate 0.375 % w/v
as Chlorhexidine Digluconate Solution

Excipients:

Ponceau 4R (E124) 0.0025 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Teat dip/teat spray solution.
A clear red liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cattle.

4.2 Indications for use, specifying the target species

As an aid in the prevention of mastitis in lactating cows.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Wash udder and teats before milking.

4.5 Special precautions for use

Special precautions for use in animals

For external use only.

Dip the full length of the teats.

After completion of milking discard remaining solution from the teat dip cup. Wash out the teat cup before re-use.

Special Precautions to be taken by the Person Administering the Product to Animals

- In case of ingestion, obtain medical attention as soon as possible.
- In case of contact with eyes, rinse immediately with water and seek medical advice.
- Wash hands after use.
- Avoid working in spray mist.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

This product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical administration to the teats.

Use Alfa Red undiluted immediately after milking.

Spray the entire surface or dip the full length of each teat.

Spraying: Use immediately after milking. Spray the entire surface of the teats.

Dipping: Use immediately after milking. Dip the full length of the teats.

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

Not applicable.

4.11 Withdrawal Period(s)

Nil withdrawal period for milk and slaughter of treated animals.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiseptics and disinfectants, Biguanides and amidines

ATCvet Code: QD08AC02

5.1 Pharmacodynamic properties

Alfa Red is an antiseptic. The active form of this product is chlorhexidine gluconate. It's activity is based on the cationic molecule binding to extra microbial complexes and relatively charged microbial cell walls altering the cells' osmotic equilibrium.

The mode of action involves rapid attraction to the bacterial cell, absorption to phosphate compounds on the bacterial surface, overcoming the cell wall exclusion mechanisms, attraction towards the cytoplasmic membrane, leakage of low molecular weight cytoplasmic components and precipitation of the cytoplasm by the formation of complexes with phosphated moieties.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of chlorhexidine gluconate are summarised in the chlorhexidine summary report issued by the Committee for Veterinary Medicinal Products. Literature suggests that chlorhexidine gluconate is poorly absorbed after oral or topical application (described in the summary report of chlorhexidine). Therefore information relating to distribution, biotransformation, and elimination is not applicable for this application.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol (70%)
Isopropyl Alcohol
Ponceau 4R (E124)
Macrogol Lauryl Ether
Simeticone
Purified Water

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

6.4 Special precautions for storage

- Do not store above 25 °C.
- Store upright in tightly closed original container.
- Store away from food, drink and animal foodstuffs.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is packaged in 5, 10, 20, 25, 60 or 200 litre, polyethylene containers with a polyethylene cap and safety-sealing ring.

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

Harmful to fish - do not contaminate ponds, waterways and ditches with the product or empty container.

Wash out empty container thoroughly and dispose of safely.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

DeLaval Ireland Ltd.
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Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10908/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th October 2008

10 DATE OF REVISION OF THE TEXT