SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Megorex 0.436% w/v Ready To Use Teat Dip and Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition

Active Substance
Chlorhexidine Gluconate
(as Chlorhexidine Gluconate
Solution)

Excipients
Benzalkonium chloride
Ponceau 4R (E124)

Other Relevant Constituents
Glycerol
Sorbitol

For full list of excipients see 6.1.

3. PHARMACEUTICAL FORM

Teat Dip/Teat Spray solution.
Red 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

Not to be use on lacerated teats.

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.

For use as a post-milking teat dip/spray only.

ii. Special precautions for the person administering the veterinary medicinal product to animals.
Avoid contact with eyes. If sprayed/splashed in the eye, rinse with clean running water and seek medical advice.
In case of ingestion seek medical attention immediately.
When used as a spray, avoid working in the spray mist.
Do not eat, drink or smoke whilst using this product.
Keep away from animal feed.
Wash hands after use.

iii Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

None recorded.

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

Incompatible with other dip compounds particularly anionics and soaps.
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 with the dip. No dilution is required
Dip teats of every cow immediately after each cow is milked, ensuring that the full length of each teat is covered. Top up the cup with fresh solution as required.

Teat spraying:
Immediately after milking spray the entire surface of each teat of every cow with the product. No dilution is required.

Udder washing and cluster dipping:
Use in the proportion of 150ml of the product to 10 litres of water. 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. Dry each teat thoroughly after washing using either separate cloths or disposable

paper towels for each cow. Teat clusters should be immersed and agitated for at least 30 seconds and rinsed in clean water before milking each cow. Teat dip cups should be emptied and washed before re-use.

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: Antiseptics and disinfectants, biguanides and amidines

ATC Vet Code: QD08AC02

5.1 Pharmacodynamic properties

Chlorhexidine is a bisbiguanide antiseptic and disinfectant effective against a wide range of bacteria, some fungi, and some viruses.

It is more effective against Gram-positive than Gram-negative bacteria, some species of *Pseudomonas* and *Proteus* being less susceptible. It inhibits mycobacteria. Chlorhexidine inhibits some viruses and is active against some fungi. It is inactive against bacterial spores at room temperature.

For pre-operative skin disinfection and hand washing, chlorhexidine is used as a 0.5% solution of the acetate or gluconate in alcohol (70%) or as in a 4% detergent solution of the gluconate.

For disinfection of wounds, burns, or other skin damage disorders, chlorhexidine is used as a 0.05% aqueous solution of the gluconate.

5.2 Pharmacokinetic properties

Chlorhexidine is poorly absorbed from the gastro-intestinal tract and skin.

Chlorhexidine was detected in low concentrations in the venous blood of 5 of 24 infants after bathing with a preparation containing chlorhexidine gluconate 4%. No adverse effects due to percutaneous absorption of chlorhexidine were observed.

Low concentrations have been found in the venous blood of neonates following the topical use of a powder containing chlorhexidine 1%.

Percutaneous absorption of chlorhexidine was reported in pre-term neonates (but not full term infants) treated with chlorhexidine 1% in alcohol for neonatal cord care; no such absorption occurred when a dusting powder containing

chlorhexidine 1% and zinc oxide 3% was used.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Glycerol
Sorbitol
Ponceau 4R (E124)
Alcohol (C_{13} C_{15}) 11 Mole Ethoxylate
Isopropyl Alcohol
Water Deionised

6.2 Incompatibilities

Chlorhexidine gluconate is incompatible with soaps and other anionic materials and with suspending agents such as alginates and tragacanth. At concentrations of 0.05% chlorhexidine salts are incompatible with borates bicarbonates, carbonates, chlorides, citrates, nitrates, phosphates and sulphates, forming salts of low solubility. Insoluble salts may form in hard water. Chlorhexidine is inactivated by cork.

a) Soaps
b) Anionic surfactants
c) Phenolic disinfectants

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. Protect from frost. If contents freeze they must be thawed and thoroughly mixed before use. Do not store above 25°C.

6.5 Nature and composition of immediate packaging

* 200 litre, opaque, white, blue, grey, green or colourless high density polyethylene drum with two polypropylene co-polymer bungs.

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 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 used container.

7. MARKETING AUTHORISATION HOLDER

Evans Vanodine International Plc.
Brierley Road
Walton Summit
Preston
Lancashire
PR5 8AH

8. MARKETING AUTHORISATION NUMBER

Vm 03940/4065

9. DATE OF FIRST AUTHORISATION

12 September 2000

10. DATE OF REVISION OF THE TEXT

March 2016

Approved: 16 March 2016