SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active Substance	
Chlorhexidine Gluconate (as Chlorhexidine Gluconate solution)	0.436% w/v
Excipients	
Benzalkonium chloride	0.010% w/v
Ponceau 4R (E124)	0.0021% w/v
Other Relevant Constituents	
Glycerol	4.50% w/v
Sorbitol	0.50% w/v

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 used on lacerated teats.

4.4 Special warnings for each target species

See Section 4.8.

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only. 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 immediately.
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 Masodip.
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 Masodip. No dilution is required.

Udder washing and cluster dipping - Use in the proportion of 150ml Masodip
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 eitherseparate 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 after topical or oral application.
In oral dosing studies in rats (5 and 50 mg/kg bw), dogs (0.05 and 5 mg/kg bw), marmosets (6.6 and 7.3 mg/kg bw) and rhesus monkeys (5.5 mg/kg bw) using ^{14}C-labelled chlorhexidine oral bioavailability was estimated to be less than 1%.
In all these species, over 90% of the administered doses were recovered from faeces and only 0.2 – 1.3% from urine. In rats biliary excretion was less than 2%. The one major component found in faeces was unmetabolised chlorhexidine.
No detectable residues were found in blood samples taken from 5 neonatal Rhesus monkeys bathed daily for 90 days in a cleanser containing 8% chlorhexidine gluconate (LOD was 0.011ug/ml). Residues were found in samples of 2 (out of 5) samples of fat (19ug/kg), all 5 kidney samples (18-44 ug/kg) and 1 liver sample (17ug/kg). Residues were appreciable in skin

(70-200 ug/kg). No chlorhexidine was detected in the blood of human infants washed in a 4% chlorhexidine solution (LOD:0.1 ug/ml). Studies in adult volunteers failed to detect chlorhexidine in blood samples after a single topical application of a 5% solution of ^{14}C-labelled chlorhexidine to 50cm^2 of skin (LOD 0.005 ug/ml) or repeated daily use over 6 months as a pre-operative “scrub” (LOD 0.01 ug/ml).

Reference: Committee for Veterinary Medicinal Products EMEA/MRL/107/96-FINAL Chlorhexidine Summary Report.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Ponceau 4R (E124)
Glycerol
Sorbitol
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. Do not store above 25°C.
If contents freeze they must be thawed and thoroughly mixed before use.

6.5 Nature and composition of immediate packaging

1000 litre natural UN approved high density intermediate bulk container (IBC) with tap.
Ensure that all equipment and containers used for decanting not more than enough product for use that day, are fit for purpose, clean, emptied after

use and washed before use.

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

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 and 1000 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.
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 03940/4008

9. DATE OF FIRST AUTHORISATION

20 December 1991

10. DATE OF REVISION OF THE TEXT

March 2016

Approved: 16 March 2016