SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deosan SummerTeatcare Plus (0.425%w/w) Teat dip and Teat Spray Emulsion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	Quantitative composition %w/w
Chlorhexidine gluconate (As Chlorhexidine gluconate solution)	0.425 2.25
<u>Excipients</u>	
Ponceau 4R(E124)	0.001% w/w
For full list of excipients see section 6.1	
Other Relevant Constituents	
Glycerol	3.0% w/w
PHARMACEUTICAL FORM	

Teat dip and teat spray emulsion A pink liquid

4. CLINICAL PARTICULARS

4.1 Target species

3.

Cattle - milking cows

4.2 Indications for use, specifying the target species

A ready to use teat dip/spray solution for use as an aid in the control of bovine mastitis

4.3 Contraindications

Not applicable

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only Wash and dry udders and teats before milking

ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid contact with eyes. In case of eye contact, rinse with clean running water immediately. Do not eat, drink or smoke whilst using the product In case of ingestion seek medical advice immediately. When used as a spray, avoid working in spray mist Keep away from animal feed Wash hands after use

iii. Other precautions

none

4.6 Adverse reactions (frequency and seriousness)

Very rare, change of active ingredient teat dip type can on very rare occasions cause skin irritation

4.7 Use during pregnancy, lactation or lay

Use as required

4.8 Interaction with other medicinal products and other forms of interaction

This disinfectant is inactivated by soaps and anionic disinfectants

4.9 Amount(s) to be administered and administration route

This product is used without dilution

Teat Dipping

Directly after milking each cow, dip the full length of each teat in the product Replenish the teat dip cup as necessary Teat dip cups should be emptied after milking and washed before re –use

<u>Spraying</u>

Immediately after milking, spray the entire surface of each teat with the product

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

Not applicable for the intended mode of application

4.11 Withdrawal period(s)

Meat –zero days milk - zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Products for teats and udder, Disinfectants

ATC Vet Code: QG52A

Teat dips

5.1 Pharmacodynamic properties

Chlorhexidine is recognised as a broad spectrum biocide active against common mastitis causing bacteria. The mode of action involves rapid attraction to the bacterial cell wall and absorption to phosphate compounds on the bacterial surface

5.2 Pharmacokinetic properties

Because of its cationic nature, chlorhexidine bonds strongly to skin and mucosa. It is therefore poorly absorbed after oral or topical application. Chlorhexidine is of low toxicity. Residues in milk from use as a teat dip or spray have been demonstrated to be low

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ponceau 4R (E124) colourant Glycerol Paraffin Liquid Light Isotridecanol 8 mole ethoxylate Isotridecanol 12 mole ethoxylate Alcohol (C13-15) 3 mole ethoxylate Isopropyl alcohol Dimethyl Phthalate Ethohexadiol Water deionised

6.2 Incompatibilities

Chlorhexidine is incompatible with soaps and other anionic materials. Do not mix with other chemicals or teat dips

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 ⁰ C Protect from frost Protect from direct sunlight Store in tightly closed original container

6.5 Nature and composition of immediate packaging

25 litre or 200 litre white or blue high density polyethylene drum with high density polyethylene or polypropylene cap (screw fit)

20 litre blue, white or natural opaque high density polyethylene drums with black high density polyethylene caps (screw fit) (tamper evident) with expanded polyethylene gasket

1000 litre (950 litre fill) white opaque high density polyethylene IBC (Intermediate bulk container) with black high density polyethylene cap (screw fit) (with degassing device) and with natural expanded rubber seal.

For the 1000 litre container, 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 re –use

The 200 litre 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

Dispose in accordance with local requirements HARMFUL to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container

7. MARKETING AUTHORISATION HOLDER

Diversey Limited Weston Favell Centre Northampton NN3 8PD

8. MARKETING AUTHORISATION NUMBER(S)

Vm 15985/4011

9. DATE OF FIRST AUTHORISATION

Date: 18th July 1990

10. DATE OF REVISION OF THE TEXT

Date: October 2011