SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deosan Super Iodip Iodine 2 % w/v Concentrate Teat Dip and Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	<u>%w/v</u>
lodine	2.0

Other Relevant Constituents		
Glycerol	15.82	
Sorbitol Solution 70%w/w (Non crystallising)	15.82	

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for TeatDip/Teat Spray solution A clear homogeneous dark brown liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle - milking cows

4.2 Indications for use, specifying the target species

A dilutable teat dip/spray 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

Wash and dry udders and teats before milking. Teat dip cups should be emptied after milking and washed before reuse.

These are both important aspects of good hygiene and mastitis

control. For external use only.

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

When used as a spray, avoid working in spray mist. Do not eat, smoke or drink while using the product. Wash hands and exposed skin after use. Avoid contact with eyes. In the case of contact with eyes rinse with clean water for at least 10 minutes and seek medical advice immediately. In case of ingestion, seek medical attention immediately. Keep away from food, drink and animal feed.

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

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

The use of the product has no known interactions with other products, including cow diet supplements. Do not mix with other chemicals.

4.9 Amount(s) to be administered and administration route

This product is diluted before use. Prepare a fresh solution daily

Teat dipping:

Add 1 part product to 3 parts of clean water and mix well

Directly after milking each cow, dip the full length of each teat in the product. The teat cup should be kept topped up as necessary.

Teat spraying:

Add 1 part product to 4 parts of clean water and mix well

Directly after milking each cow, 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)

Withdrawal period for meat/milk - zero days/hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Products for teats and udder, Disinfectants

ATC Vet Code: QG52A

Teat dips

5.1 Pharmacodynamic properties

lodine based teat dips have broad spectrum antibacterial action against mastitis causative organisms. The microbiological action of iodine appears to be due to an oxidative – reductive reaction involving various cell wall constituents which are irreversibly transformed. It appears sulfhydryl linkages, in bacterial cell wall components are specifically targeted by the iodine.

5.2 Pharmacokinetic properties

The absorption of iodine through the skin from teat dipping applications is well below levels which would indicate pharmokinetic activity of the type described in the committee for veterinary medicinal products summary report on iodine.

5.3 Environmental properties

lodine based teat dips are harmful to fish and aquatic life. Ponds, watercourses or ditches must not be contaminated with the product or used containers. The impact of the active ingredient (iodine) entering the environment via normal use of the product is low

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Sorbitol Solution70% w/w (non crystallising) Linear alcohol ethoxylate Citric acid monohydrate Sodium hydroxide Sulphuric acid (for pH adjustment) Water demineralised

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Do not store above 25°C. Protect from direct sunlight. Store in tightly closed original container. Protect from frost Discard any remaining unused ,diluted product

6.5 Nature and composition of immediate packaging

5 litre, white opaque , high density polyethylene jerrican, with a white, opaque, high density polyethylenetamper evident cap (screw fit) 20 litre, blue or white opaque, high density polyethylene drum, with a black high density polyethylene cap (screw fit) (tamper evident) with expanded polyethylene gasket

25 litre, white opaque high density polyethylene jerrican with a grey, opaque, high density polyethylene tamper evident cap (screw fit) with an ethylene, propylene, dienterpolymer washer.

200 litre , blue, opaque, high density polyethylene drum , with a white polypropylene tamper evident cap (scew fit) , with ethylene propylene dienterpolymer washer

The 200 litre container 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

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. 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.

7. MARKETING AUTHORISATION HOLDER

Diversey Limited Weston Favell Centre Northampton Northamptonshire NN3 8PD

8. MARKETING AUTHORISATION NUMBER(S)

Vm 15985/4007

9. DATE OF FIRST AUTHORISATION

Date: 13 June 1984

10. DATE OF REVISION OF THE TEXT

Date: October 2011