

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Deosan Super Iodip.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Iodine 2.00 % w/v

Excipients

Glycerol 15.82 % w/v

Sorbitol Solution 15.82 % w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat dip. Brown coloured teat dip concentrate.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows.

4.2 Indications for use, specifying the target species

As an aid in the control of bovine mastitis.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Teat dip cups should be emptied after milking and washed before reuse.

Wash udders and teats before milking, preferably with an individual towel.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Do not breathe spray.

Wash hands after use.

In the case of contact with eyes give prolonged irrigation with clean water for at least 10 minutes and get medical advice immediately.

If the milker is allergic or idiosyncratic towards iodine you are recommended to change to a non-iodine formulation

4.6 Adverse reactions (frequency and seriousness)

None except that excessive use of surfactant based iodophor products can lead to defatting of skin. This effect is unlikely when used as directed.

4.7 Use during pregnancy, lactation or lay

This product may be used on 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 external use only.

This is a concentrated formulation: dilute with water before use.

Teat dipping

Dilute one part of Super Iodip with three parts of clean water and mix well. Directly after milking each cow, dip the full length of each teat in the diluted solution. The teat cup should be kept topped up during milking.

Teat spraying

Dilute one part Super Iodip with four parts of clean water and mix well. Directly after milking each cow, spray the entire surface of each teat with the diluted solution.

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

Not applicable for the intended mode of application.

4.11 Withdrawal Period(s)

Meat: Nil.

Milk: Nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Bactericidal action.

Emollient.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

Sorbitol solution (70%)

Alcohol (C13) 12 mole ethoxylate

Sodium hydroxide solution (48%)

Citric acid anhydrous

Sulphuric acid

Deionised 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: 18 months.

6.4 Special precautions for storage

Do not store above 25°C.

Protect from direct sunlight.

Protect from frost.

Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

The product is packaged in a 5 litre, high density polyethylene (HDPE) container and closure, a 20 litre HDPE container and closure or a 210 litre high molecular weight, high density polyethylene drum with polypropylene bung (closure).

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

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

Empty containers should be made unusable by crushing or putting holes in them.

Unused product and empty containers should be disposed of in accordance with any guidance from an appropriate waste regulation authority.

7 MARKETING AUTHORISATION HOLDER

Diversey Hygiene Sales Limited

Jamestown Rd.,

Finglas,

Dublin 11.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10457/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

April 2012