Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovidip 2% w/v Concentrate for Teat Dip or Spray Solution for bovine.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Iodine, 2% w/v

2 g per 100 ml as available iodine (concentrate).

25 mg per 5 ml dose as available iodine (ready-to-use solution).

Excipients:

Emollients: Glycerol, 10% w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Concentrate for Teat Dip or Spray Solution.
Clear Brown Liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Bovine.

4.2 Indications for use, specifying the target species

Teat disinfection as an aid in the prevention of mastitis in lactating dairy cows.

4.3 Contraindications

Do not use in cases of known hypersensitivity to iodine, or to any of the excipients.
Do not mix with other chemicals.

4.4 Special warnings for each target species

Prior to milking, wash teats with an udder wash solution and dry with a disposable paper towel.
Discard any product that becomes contaminated.

4.5 Special precautions for use

Special precautions for use in animals

Allow product to dry before exposing the cows to wet (rainy), cold or windy conditions.
Use in injured teats may delay the wound-healing process. It is recommended that treatment be discontinued until teat lesions have resolved.
If signs of disease persist or appear, consult a veterinary surgeon.

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

Care should be taken avoid eye contact. In case of eye contact, flush the eyes with copious amounts of water and seek medical advice.
In case of ingestion, drink large quantities of water and obtain medical attention as soon as possible.
When used as spray, avoid working in spray mist.
Wash hands after use.
Persons with iodine allergy should wear gloves and mask.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Indicated for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

The use of this product in the specified manner (topical antiseptic) has no known interactions with other medicaments or nutrition.

4.9 Amounts to be administered and administration route

Dilute before use. Prepare a fresh solution daily. Dilute one part of Bovidip 2% w/v Concentrate for Teat Dip or Spray Solution with three parts of clean water and mix well. Always clean the dip cup or spray container after use.
Amounts to be administered: about 5 ml per cow per application.
Administration route:

- Dipping: Dip each teat immediately after milking in a teat dip cup containing diluted product. Dip the full length of the teats and replenish the dip cup as necessary.
- Spraying: Spray the entire surface of the teats after each milking.

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

Not applicable. The product is for topical application. Significant absorption does not occur.

4.11 Withdrawal Period(s)

Meat: Zero days.
Milk: Zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Products for teats and udders: Disinfectants
ATC Vet Code: QG52A

5.1 Pharmacodynamic properties

Iodine solutions react with the organic matter of bacteria and viruses to render them harmless. The mechanism of kill appears to be due to an oxidative-reductive reaction, involving various cell wall constituents, which are irreversibly transformed. The sulphydryl linkages, in bacterial cell wall components, are specifically targeted by iodine.

Bovidip 2% w/v Concentrate for Teat Dip or Spray Solution is bactericidal (EN 1040 and EN 1656) against:
Pseudomonas aeruginosa
Staphylococcus aureus
Enterococcus hirae
Proteus vulgaris

5.2 Pharmacokinetic properties

Literature suggests that absorption of iodine through the skin is well below levels which would lead to pharmacokinetic activity in the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water Purified
Glycerol
Macrogol lauryl ether
Poloxamer
Sodium iodide
Citric acid monohydrate
Sodium hydroxide

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.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution according to directions: 1 day.

6.4 Special precautions for storage

Store upright in the tightly closed original container.
Do not store above 25°C.
Protect from frost.
If the product has frozen, thaw in a warm place and shake well before use. For the larger pack sizes, the product should be rolled sufficiently to mix the solution. Under no circumstances should an attempt be made to shake the 60 or 200 litre packs.
Protect from light.

6.5 Nature and composition of immediate packaging

- High-density polyethylene 5, 10, 20, 60 or 200 litre cans closed with high-density polyethylene screw caps, secured with a sealing ring.
- 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 products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

DeLaval NV
Industriepark-Drongen 10
B-9031 Gent
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10827/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th July 2007

Date of last renewal: 9th July 2012

10 DATE OF REVISION OF THE TEXT

August 2014