SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovidip 0.5% w/w Teat Dip or Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: iodine, 0.5% w/w
Other Relevant Constituents : glycerol, 10% w/w

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Teat Dip or Teat Spray Solution
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. Contra-indications

Do not use in cases of known hypersensitivity to iodine.
Do not mix with other chemicals.

4.4. Special warnings for each target species

Ensure udder and teats are clean and dry before each milking.
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.
Discard any product that becomes contaminated.
If signs of disease persist or appear consult a veterinary surgeon.

4.5. Special precautions for use

i) Special precautions for use in animals

None

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

Care should be taken to 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.

iii) Other precautions

None

4.6. Adverse reactions

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

Amounts to be administered: 5 ml per cow per application.
Administration route: Dip each teat immediately after milking in a teat cup containing undiluted product. Dip the full length of the teats and replenish the dip cup as necessary. Always clean the cup after use. Alternatively, spray the entire teats after each milking.

4.10. Overdose

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

4.11. Withdrawal periods

Meat / Milk: Zero days/hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiseptics and disinfectants, Iodine products
ATCVet code: QD08AG03

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.

5.2. Pharmacokinetic particulars

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

Glycerol
Water purified
Alcohol (C12) 12 Mole Ethoxylate
Sodium iodide
Citric acid monohydrate
Sodium hydroxide 29%

6.2. Incompatibilities

As a general precaution it is advisable not to mix Bovidip 0.5% w/w Teat Dip or Teat Spray Solution with other products.

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°C.
Store upright in the tightly closed original container.
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.
Not all pack sizes may be marketed.

(*) The 200 litre container should not be returned for re-filling.

6.6. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

Any unused product or waste material should be disposed of in accordance with national requirements. To dispose of unused product to land you must have an authorisation under the Groundwater Regulations 1998.

7. MARKETING AUTHORISATION HOLDER

DeLaval NV
Industriepark-Drongen 10
B-9031 Gent
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm: 17140/4007

9. DATE OF THE FIRST AUTHORISATION

Date: 05 July 2007

10. DATE OF REVISION OF THE TEXT

Date: May 2014


03 June 2014