

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovidip 20 mg/ml Concentrate for Teat Dip or Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

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

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

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Water Purified	
Glycerol	100 mg/ml
Macrogol lauryl ether	
Poloxamer	
Sodium iodide	
Citric acid monohydrate	
Sodium hydroxide	

Clear Brown Liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dairy cattle).

3.2 Indications for use for each target species

Teat disinfection as an aid in the prevention of mastitis.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Do not mix with other chemicals. Prior to milking, wash teats with an udder wash solution and dry with a disposable paper towel. Discard any product that becomes contaminated. Always use a clean spray container or dip cup and clean after use.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only. 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 to be taken by the person administering the veterinary 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 accidental ingestion, seek medical advice immediately and show the combined package leaflet and label to the physician. When used as spray, avoid working in spray mist. Wash hands after use. Persons with iodine allergy should wear gloves and mask. The use of gloves during milking and dipping or spraying is recommended to protect the skin and for hygienic milk collection.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Dilute before use. Prepare a fresh solution daily. Dilute one part of the veterinary medicinal product 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 of the diluted product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG52A

4.2 Pharmacodynamics

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.

The veterinary medicinal product is bactericidal (EN 1040 and EN 1656) against:

Pseudomonas aeruginosa

Staphylococcus aureus

Enterococcus hirae

Proteus vulgaris

4.3 Pharmacokinetics

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 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 liter packs. Protect from light.

5.4 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.

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

materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal should not enter water courses as iodine may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the product concerned.

The 200 liter container should not be returned for re-filling.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DeLaval NV

7. MARKETING AUTHORISATION NUMBER(S)

VPA: 10827/003/001

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{High-density polyethylene 5, 10, 20, 60 or 200 litre cans}

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2. COMPOSITION

Active substance:

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

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

Excipients:

Glycerol, 100 mg/ml

Clear Brown Liquid.

3. PACKAGE SIZE

5, 10, 20, 60 or 200 litre.

4. TARGET SPECIES

Cattle (dairy cattle).

5. INDICATIONS FOR USE

Indications for use

Teat disinfection as an aid in the prevention of mastitis.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Do not mix with other chemicals. Prior to milking, wash teats with an udder wash solution and dry with a disposable paper towel. Discard any product that becomes contaminated. Always use a clean spray or dip cup and clean after use.

Special precautions for safe use in the target species:

For external use only. 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 to be taken by the person administering the veterinary 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 accidental ingestion, seek medical advice immediately and show the combined package leaflet and label to the physician. When used as a spray, avoid working in a spray mist. Wash hands after use. Persons with iodine allergy should wear gloves and mask. The use of gloves during milking and dipping or spraying is recommended to protect the skin and for hygienic milk collection.

Pregnancy and lactation:

Can be used during lactation and pregnancy.

Interactions 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.

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

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

About 5 ml of the diluted product per cow per application.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Dilute before use. Prepare a fresh solution daily. Dilute one part of the veterinary medicinal product with three parts of clean water and mix well. Always clean the dip cup or spray container after use.

- 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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: zero days / Milk: zero hours.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store upright in the tightly closed original container. Do not store above 25°C. Protect from light. 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.

Do not use this veterinary medicinal product after the expiry date which is stated on this label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as iodine may be dangerous for fish and other aquatic organisms. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

The 200 L container should not be returned for re-filling.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number:

Pack sizes

5, 10, 20, 60 or 200 litres high-density polyethylene drums with screw closures and seals. Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

09/01/2025

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

DeLaval NV, Industriepark-Drongen 10, 9031 Gent, Belgium. PHV phone number: 0032 9 351 24 27

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Batch number and expiry date: see label top of can.

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 6 months.

Shelf life after dilution according to directions: 1 day.

21. BATCH NUMBER

Batch number and expiry date: see label top of can.

Lot {number}