

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proactive 1.52 mg/mL Teat Dip/Spray Solution

[Boviqarai 1.52 mg/mL Teat Dip/Spray Solution (SE, NO, EE, LT, DK, ES, FR, FI)]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One mL contains :

Active substance:

Iodine 1.52 mg

Excipients:

Qualitative composition of excipients and other constituents
Citric acid monohydrate
Glycerol
Sodium iodate
Sodium chloride
Sodium hydroxide
Sorbitol, liquid (non-crystallising)
Xanthan Gum
Sodium iodide
Poloxamer 335
Polysorbate 80
Purified water

A red-brown liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dairy cows).

3.2 Indications for use for each target species

Teat disinfection as part of a strategy to reduce the incidence of mastitis in lactating cattle (mastitis prophylaxis).

3.3 Contraindications

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

3.4 Special warnings

The presence of milk or dirt neutralizes iodine, reducing its activity and effectiveness. Ensure that the udder and teats are clean and dry before the next milking.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only.

Use in injured teats may delay wound healing process. It is recommended that treatment be discontinued until teat lesions have resolved.

Allow the veterinary medicinal product to dry before the cows are exposed to rain, cold or windy weather conditions

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

People with known hypersensitivity to iodine or to any of the excipients should avoid contact with the veterinary medicinal product. If you develop symptoms following exposure, such as skin rash you should seek medical advice and show the combined package leaflet and label to the physician.

Avoid ingesting the veterinary medicinal product. In case of accidental ingestion seek medical advice immediately and show the combined package leaflet and label to the physician.

Do not eat, drink or smoke while using the veterinary medicinal product. When used as spray, avoid working in spray mist. This veterinary medicinal product might be mildly irritating to skin and eyes.

Avoid contact with skin and eyes when administering the veterinary medicinal product. During application avoid contact with hands or wear protective gloves. If the veterinary medicinal product comes into contact with the eyes, rinse immediately with plenty of water.

Wash hands after use.

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 its local representative 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 veterinary medicinal product must not be used concurrently with other teat disinfectants or care products.

3.9 Administration routes and dosage

Teat use.

Amounts to be administered: 5 ml per cow per application.

The veterinary medicinal product is meant to be used as a post-milking teat dip or spray up to two times per day. The duration of treatment is not limited.

Dip each teat of the cow immediately after milking in a dip cup containing undiluted veterinary

medicinal product. Alternatively, spray the entire teats after each milking. Spraying must be done from below the teat. Ensure that the teat is covered to three quarters length and replenish the dip cup or spray container as necessary.

The dip cup or spray container should be emptied after each milking and washed before reuse.

Ensure udder and teats are clean and dry before each milking.

If the veterinary medicinal product has frozen, thaw in a warm room and shake well before use.

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

Not applicable, veterinary medicinal 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:

QD08AG03

4.2 Pharmacodynamics

. The veterinary medicinal product is an antiseptic. The active form of this product is the free (molecular) iodine. The mechanism of kill appears to be due to an oxidative reductive reaction, involving various cell wall constituents, which are irreversibly transformed. It appears sulphhydryl linkages, in bacteria cell wall components, are specifically targeted by the iodine. The veterinary medicinal product has been tested according to European Standards 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 or alkalis or reducing substances.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 1 year.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Opaque high-density polyethylene barrel of 5, 10, 20, 60 or 200 litre, with high-density polyethylene screw caps. 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

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 veterinary medicinal product concerned.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DeLaval NV

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription. [IE, BE, DE, AT, CZ, NL, UK(NI), CY, BG, DK, EE, ES, FI, HU, HR, IS, IT, LT, LU, LV, NO, PT, RO, SE, SL, SK]

Veterinary medicinal product subject to veterinary prescription except for some pack sizes [FR]

Veterinary medicinal product subject to prescription. [EL, PL]

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

{5, 10, 20, 60 or 200 litre, high-density polyethylene barrels with high-density polyethylene screw caps }

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2. COMPOSITION

One mL contains:

Active substance:

iodine 1.52 mg.

A red-brown liquid.

3. PACKAGE SIZE

5, 10, 20, 60 or 200 litres.

4. TARGET SPECIES

Cattle (dairy cows).

5. INDICATIONS FOR USE

Indications for use: Teat disinfection as part of a strategy to reduce the incidence of mastitis in lactating cattle (mastitis prophylaxis).

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:

The presence of milk or dirt neutralizes iodine, reducing its activity and effectiveness.

Ensure that the udder and teats are clean and dry before the next milking.

Special precautions for safe use in the target species: For external use only. Use in injured teats may delay the wound-healing process. It is recommended that treatment be discontinued until teat lesions have resolved. Allow the veterinary medicinal product to dry before the cows are exposed to rain, cold or windy weather conditions.

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

People with known hypersensitivity to iodine or to any of the excipients should avoid contact with the veterinary medicinal product. If you develop symptoms following exposure, such as skin rash you should seek medical advice and show the combined package leaflet and label to the physician. Avoid ingesting the veterinary medicinal product. In case of accidental ingestion seek medical advice immediately and show the combined package leaflet and label to the physician. Do not eat, drink or smoke while using the veterinary medicinal product. When used as spray, avoid working in spray mist. This veterinary medicinal product might be mildly irritating to skin and eyes. Avoid contact with skin and eyes when administering the veterinary medicinal product. During application avoid contact with hands or wear protective gloves. If the veterinary medicinal product comes into contact with the eyes, rinse immediately with plenty of water. Wash hands after use.

Pregnancy and lactation: Can be used during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction: The veterinary medicinal product must not be used concurrently with other teat disinfectants or care products Major incompatibilities: In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products or alkalis or reducing substances.

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 or its local representative 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: Teat use. Amount to be administered: 5 ml per cow per application.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration:

The veterinary medicinal product is meant to be used as a post-milking teat dip or spray up to two times per day. The duration of treatment is not limited. Dip each teat of the cow immediately after milking in a dip cup containing undiluted veterinary medicinal product. Alternatively, spray the entire teats after each milking. Spraying must be done from below the teat. Ensure that the teat is covered to three quarters length and replenish the dip cup or spray container as necessary. The dip cup or spray container should be emptied after each milking and washed before reuse. Ensure udder and teats are clean and dry before each milking.

If the veterinary medicinal product has frozen, thaw in a warm room and shake well before use.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

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.

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

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS
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Classification of veterinary medicinal products:

Veterinary medicinal product not subject to prescription.[IE, BE, DE, AT, CZ, NL, UK(NI), CY, BG, DK, EE, ES, FI, HU, HR, IS, IT, LT, LU, LV, NO, PT, RO, SE, SL, SK]

Veterinary medicinal product subject to veterinary prescription except for some pack sizes [FR]

Veterinary medicinal product subject to prescription. [EL, PL]

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number:**Pack sizes:**

Opaque high-density polyethylene barrel of 5, 10, 20, 60 or 200 litre, with high-density polyethylene

screw caps. Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised: {MM/YYYY}

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

18. OTHER INFORMATION

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19. THE WORDS “FOR ANIMAL TREATMENT ONLY”
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For animal treatment only.

20. EXPIRY DATE

Batch number and expiry date: see label top of the barrel. Shelf life after first opening the immediate packaging: 1 year.

21. BATCH NUMBER

Batch number and expiry date: see label top of the barrel.