1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proactive 1.5 mg/g Teat Dip/Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml dose contains:

Active substance:

1.5 mg/g available iodine equivalent to 7.5 mg.

Excipients:

Qualitative composition of excipients and other constituents
Citric acid monohydrate
Glycerol
Sodium iodate
Sodium chloride
Sodium hydroxide
Sorbitol
Xanthan Gum
Sodium iodide
Poloxamer 335
Polysorbate 80
Purified water

A red-brown liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dairy).

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

None.

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 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 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 product. When used as spray, avoid working in spray mist. This product might be mildly irritating to skin and eyes. Avoid contact with skin and eyes when administering the product. If the 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 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

Other teat dip or spray solutions should not be used concurrently.

3.9 Administration routes and dosage

Amounts to be administered: 5 ml per cow per application.
The duration of treatment is not limited.
Ensure udder and teats are clean and dry before each milking.
Administration route: Dip each teat of the cow immediately after milking in a dip cup containing undiluted product. Alternatively, spray the entire teats after each milking. 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.

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

Not applicable, 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
When used as an antiseptic, 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. It appears sulfhydryl linkages, in bacteria cell wall components, are specifically targeted by the 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: 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.
If product has frozen, thaw in a warm room and shake well before using.
Protect from light.

5.4 Nature and composition of immediate packaging

A dark liquid contained in 5, 10, 20, 60 or 200 litre, opaque high-density polyethylene drums with screw closures and seals. 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)

VPA 10827/001/001

8. DATE OF FIRST AUTHORISATION

11/01/2002

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

20/08/2024

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).