SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proactive 0.15% w/w Teat Dip/Spray Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Available iodine	0.15% w/w
Equivalent to	1.5 mg/g
Or	7.5 mg per 5 ml dose

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Teat dip/spray solution.
A red-brown liquid.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle (dairy).

4.2. Indications for use, specifying the target species

Teat disinfection to aid in the prevention of mastitis.

4.3. Contraindications

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

4.4. Special warning for each target species

None.

4.5. Special precautions for use

i) Special precautions for use in animals

- 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 product to dry before the cows are exposed to rain, cold or windy weather conditions.

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

- Persons with known hypersensitivity to iodine or to any of the excipients should avoid using the product.
- If you develop symptoms following exposure, such as skin rash you should seek medical advice and show the label to the physician.
- Avoid ingesting the product. In case of accidental ingestion seek medical advice immediately and show the 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.

4.6. Adverse reactions

None known.

4.7. Use during pregnancy, lactation or lay

Indicated for use in lactating and pregnant cattle.

4.8. Interaction with other medicinal products and other forms of interaction

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

4.9. Amounts to be administered and administration route

- 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.

4.10. Overdose

Not applicable, product is for topical application, significant absorption does not occur.

4.11. Withdrawal period(s)

Meat and offal: Zero days
Milk: Zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: `dermatologicals; Antiseptics and disinfectants; iodine products'.
ATCvet code: QD08AG03

The veterinary medicinal product is an iodophor antiseptic. The active form of this product is free (molecular) iodine. Iodophors are solutions of iodine stabilised by the addition of surfactants or polyvinylpyrrolidone.

5.1. Pharmacodynamic properties

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

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

Citric acid monohydrate
Glycerol
Poloxamer 335
Polysorbate 80
Sodium iodate
Purified water
Sodium chloride
Sodium hydroxide
Sodium iodide
Sorbitol
Xanthan gum

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: 30 months .
Shelf life after first opening in the immediate packaging: 1 year.

6.4. 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.

6.5. 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

DeLaval NV
Industriepark - Drongen 10
9031 Gent
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 17140/4000

9. DATE OF THE FIRST AUTHORISATION

05 July 2000

10. DATE OF REVISION OF THE TEXT

March 2017

D Austin

Approved: 03 March 2017