

LABEL

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE >

{5, 10, 20, 60 or 200 litre, opaque high-density polyethylene drums with screw closures and seals }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proactive 0.15% w/w Teat Dip/Spray Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

Available iodine 0.15 % w/w

Equivalent to 1.5 mg/g

or 7.5 mg per 5 ml dose

A red-brown liquid

3. PHARMACEUTICAL FORM

Teat dip/spray solution.

4. PACKAGE SIZE

5, 10, 20, 60 or 200 litre. Not all pack sizes may be marketed.

5. TARGET SPECIES

Cattle (dairy).

6. INDICATION(S)

Teat disinfection to aid in the prevention of mastitis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Ensure udder and teats are clean and dry before each milking. 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. Use 5 ml per cow per application. The duration of the treatment is not limited.

8. WITHDRAWAL PERIOD

Meat and offal: Zero days
Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

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.

Contraindications:

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

Interaction with other medicinal products and other forms of interaction:

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

User warnings :

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.

Incompatibilities:

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

Use during pregnancy, lactation or lay:

Indicated for use in lactating and pregnant cattle

. Adverse reactions:

If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

10. EXPIRY DATE

Batch number and expiry date: see label top of the can. Do not use this veterinary medicinal product after the expiry date which is stated on the top of the can after EXP. The expiry date refers to the last day of that month.

11. SPECIAL STORAGE CONDITIONS

Store upright in the tightly closed original container. Do not store above 25 ° C. Protect from light. Protect from frost. If frozen, thaw in a warm room and shake well before using.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. Free.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

DeLaval NV
Industriepark - Drongen 10
9031 Gent
Belgium

Manufacturer responsible for batch release: DeLaval NV, Industriepark-Drongen 10, 9031 Gent, Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 17140/4000

17. MANUFACTURER’S BATCH NUMBER

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



Approved: 03 March 2017