PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proactive 1.5 mg/g Teat Dip/Spray Solution

2. COMPOSITION

Active substance:

1.5 mg/g available iodine equivalent to 7.5 mg per 5 ml dose

A red-brown liquid.

3. PACKAGE SIZE

5, 10, 20, 60 or 200 litres.

4. TARGET SPECIES

Cattle (dairy).

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:
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 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 administrating the product. If the 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: Other teat dip or spray solutions should not be used concurrently.

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 (IE: HPRA Pharmacovigilance, Website: www.hpra.ie; UK: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine, e-mail: adverse.events@vmd.gov.uk).

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

Dosage for each species, routes and method of administration: Use 5 ml per cow per treatment.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct 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. The duration of the treatment is not limited.

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. If frozen, thaw in a warm room and shake well before using.
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.
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 national collection systems applicable to the product concerned. The 200 L container should not be returned for refilling.
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:

NI: Vm 17140/3001

GB: Vm 17140/5001

Pack sizes

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

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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

Other information:

UK only: AVM-GSL

Date on which the label was revised: 06/2024

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

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

21. BATCH NUMBER

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

Gavin Hall
Approved: 11 December 2024