

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {5, 10, 20, 60 or 200 litre, high-density polyethylene barrels with high-density polyethylene screw caps }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proactive 1.52 mg/mL Teat Dip/Spray Solution

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 the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system at: 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

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

Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 17140/3001

Vm 17140/5001

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. 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

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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.