ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blockade 2.5 mg/g iodine teat dip solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Available iodine 2.5 mg/g
Equivalent to 12.8 mg per 5 ml dose

Excipients:

Qualitative composition of excipients and other constituents
Citric acid monohydrate
Glycerol
Sodium iodate
Sodium chloride
Sodium hydroxide 29%
Sorbitol solution 70%
Xanthan Gum
Sodium iodide
Poloxamer 335
Povidone K30
Purified water

Viscous red-brown liquid.

3. CLINICAL INFORMATION

3.1 Target species
Cattle (Dairy cows).

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.
The use in injured teats may delay wound healing process. It is recommended to discontinue the treatment until the teats are cured.
Allow the product to dry before the cows are exposed to wet (rainy), 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 this 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. 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

None known.

3.9 Administration routes and dosage

Dip each teat of the cow immediately after each milking in a dip cup containing undiluted product. Ensure that the teat is covered to three quarters of length and replenish the dip cup as necessary. Always clean the dip cup after its use. Dosage: 5 ml per cow per treatment.

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
The veterinary medicinal product is an antiseptic. The active form of this product is the free (molecular) iodine. Iodine solutions have a wide spectrum of activity against most bacteria species, spores of Bacillus and Clostridium and viruses. 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

The absorption of iodine through the intact skin is very low.

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

5.3 Special precautions for storage

Store upright and tightly closed in the original container.
Protect from frost.
If product has frozen, thaw in a warm room and shake well before using.
Protect from light.
Do not store above 30 °C.

5.4 Nature and composition of immediate packaging

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.

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

Medicines should not be disposed of via wastewater or household waste.
The 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 litre container should not be returned for refilling.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DeLaval NV

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10827/002/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation**:** 11 November 2002

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

06/2024

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).

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blockade 2.5 mg/g iodine teat dip solution.

2. COMPOSITION

Active substance:
Available iodine 2.5 mg/g
Equivalent to 12.8 mg per 5 ml dose
A viscous 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 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:
<u>Special precautions for safe use in the target species:</u> For external use only.
The use in injured teats may delay wound healing process. It is recommended to discontinue the treatment until the teats are cured. Allow the product to dry before the cows are exposed to wet (rainy), cold or windy weather conditions.
<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u>
People with known hypersensitivity to iodine or to any of the excipients should avoid contact with this 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. 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
<u>Pregnancy and lactation</u>: Can be used during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction: The use of this product in the specified manner (topical antiseptic) has no known interactions with other products, animal's diet and feed supplements.
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
{national system details}.

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

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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration: Dip each teat of the cow immediately after each milking in a dip cup containing undiluted product. Ensure that the teat is covered to three quarters of length and replenish the dip cup as necessary. Always clean the dip cup after its 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. Protect from frost. If product has frozen, thaw in a warm room and shake well before using. Protect from light. Do not store above 30°C.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste. The 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 litre container should not be returned for refilling.

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:

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. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised:
06/2024

Detailed information on this veterinary medicinal product is available in the Union Product Database.

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: 00*32 9 351 24 27*

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Batch number and expiry date: see label top of 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.

21. BATCH NUMBER

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