1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blockade 2.56 mg/mL teat dip solution
[Boviffens 2.56 mg/mL teat dip solution (FR, SE, NO, EE, LT, DK)]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One mL contains:
Active substance:
Iodine 2.56 mg

Excipients:

Qualitative composition of excipients and other constituents
Citric acid monohydrate
Glycerol
Sodium iodate
Sodium chloride
Sodium hydroxide
Sorbitol, liquid (non-crystallising)
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 part of a strategy to reduce the incidence of mastitis in lactating cattle (mastitis prophylaxis).

3.3 Contraindications

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

3.4 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.

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 veterinary medicinal 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 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. 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.

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

The veterinary medicinal product must not be used concurrently with other teat disinfectants or care products.

3.9 Administration routes and dosage

Teat use.

Dosage: 5 ml per cow per treatment.
Dip each teat of the cow immediately after each milking in a dip cup containing undiluted veterinary medicinal product. Ensure that the teat is covered to three quarters of length and replenish the dip cup as necessary.
This veterinary medicinal product is intended as a teat dip for use after milking and can be used up to two times per day.
The duration of the application is unlimited.
The dip cup should be emptied after each milking and cleaned thoroughly before using again.

The use of the veterinary medicinal product should be associated with an accurate udder and teat cleaning with an appropriate, moist cloth and drying of the teats prior to milking.

Do not wipe disinfectant. In very cold weather, remove the excess disinfectant at the end of the teat to prevent cracking and freezing, since sores can harbour bacteria.

If the veterinary medicinal product has frozen, thaw in a warm room and shake well before use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable, veterinary medicinal 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 veterinary medicinal product is the free (molecular) iodine. 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 has been tested according to European Standards 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 or alkalis or reducing substances.

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.
Protect from light.
Do not store above 30 °C.

5.4 Nature and composition of immediate packaging

Grey 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.

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 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DeLaval NV

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation**:** {DD/MM/YYYY}

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription. [IE, BE, DE, AT, CZ, NL, UK(NI), CY, BG, DK, EE, ES, FI, HU, HR, IS, IT, LT, LU, LV, NO, PT, RO, SE, SL, SK]
Veterinary medicinal product subject to veterinary prescription except for some pack sizes [FR]
Veterinary medicinal product subject to prescription. [EL, PL]

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 barrels }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blockade 2.56 mg/mL teat dip solution.
[Boviffens 2.56 mg/mL teat dip solution (FR, SE, NO, EE, LT, DK)]

2. COMPOSITION

One mL contains:
Active substance:
Iodine 2.56 mg
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 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.
<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 veterinary medicinal 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 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. This veterinary medicinal product might be

mildly irritating to skin and eyes. Avoid contact with skin and eyes when administrating 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 use of this product in the specified manner (topical antiseptic) has no known interactions with animal's diet and feed supplements. 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 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: Teat use. 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 veterinary medicinal product. Ensure that the teat is covered to three quarters of length and replenish the dip cup as necessary. This veterinary medicinal product is intended as a teat dip for use after milking and can be used up to two times per day. The duration of the application is unlimited.

The dip cup should be emptied after each milking and cleaned thoroughly before using again.

The use of the veterinary medicinal product should be associated with an accurate udder and teat cleaning with an appropriate, moist cloth and drying of the teats prior to milking.

Do not wipe disinfectant. In very cold weather, remove the excess disinfectant at the end of the teat to prevent cracking and freezing, since sores can harbour bacteria.

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. Protect from frost. 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 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 applicable national collection systems. These measures should help to protect the environment. 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. [IE, BE, DE, AT, CZ, NL, UK(NI), CY, BG, DK, EE, ES, FI, HU, HR, IS, IT, LT, LU, LV, NO, PT, RO, SE, SL, SK]
Veterinary medicinal product subject to veterinary prescription except for some pack sizes [FR]
Veterinary medicinal product subject to prescription. [EL, PL]

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number:

Pack sizes:
Grey 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. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised:
{MM/YYYY}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 barrel. 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 barrel.