

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blockade 0.25 % w/w iodine teat dip solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Available iodine 0.25 % w/w
Equivalent to 2.5 mg/g
or 12.8 mg per 5 ml dose

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Teat Dip Solution
Viscous red-brown liquid

4. CLINICAL PARTICULARS

4.1 Target species

(Dairy) cows

4.2 Indications for use, specifying the target species

Teat disinfection as an aid in the prevention of mastitis.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

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.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

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. 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Indicated for use in lactating and pregnant cattle.

4.8 Interaction 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable, product is for topical application, significant absorption does not occur.

4.11 Withdrawal period(s)

Meat and offal: Zero days.

Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QD08AG03

Pharmacotherapeutic group: Dermatologicals; Antiseptics and disinfectants; iodine products.

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate
Glycerol
Sodium iodate
Sodium chloride
Sodium hydroxide 29%
Sorbitol solution 70%
Xanthan Gum
Sodium iodide
Poloxamer 335
Povidone K30
Purified water

6.2 Incompatibilities

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

6.3 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

6.4 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

6.5 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.

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

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.

7. MARKETING AUTHORISATION HOLDER

DeLaval NV
Industriepark - Drongen 10
9031 Gent
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 17140/4003

9. DATE OF FIRST AUTHORISATION

25 September 2001

10. DATE OF REVISION OF THE TEXT

March 2017



Approved: 23 March 2017