# **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 or IMMUNOLOGICAL 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 properties

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 liters, 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 products or waste materials

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(S)**

VPA 10827/002/001

#### 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 10<sup>th</sup> November 2007

#### 10 DATE OF REVISION OF THE TEXT

March 2017