SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermastitis-Blocker
3 mg/ml, teat dip solution for cattle
[DK, FR, IT : Mammit-io, 3 mg/ml, teat dip solution for cattle]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance(s):
Iodine 3.08 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Teat dip solution
Liquid, dark brown solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (Lactating cows)

4.2 Indications for use, specifying the target species

Teat disinfection as part of a strategy of reduction in the incidence of mastitis in lactating cattle (mastitis prophylaxis).

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

Ensure udder and teats are clean and dry before the next milking.

4.5 Special precautions for use

Special precautions for use in animals

For external use only.
Application of this veterinary medicinal product can delay the wound healing process.
Use on injured teats is likely to involve a delay in the epithelialisation of the wound. It is therefore recommended to interrupt treatment until the wound has healed.
If the clinical signs persist, or reappear, please contact your veterinarian.
The veterinary medicinal product should have dried before treated animals are exposed to rain, cold, wind or heat.

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

This veterinary medicinal product can irritate eyes and skin. Avoid contact with the eyes. If eye contact does occur, rinse immediately with plenty of clean water, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with the skin. It is indispensable to wear impervious gloves during application. Wash exposed areas of skin.
Exposure to iodine can lead to sensitisation. This veterinary medicinal product can cause an allergic reaction in persons with a known hypersensitivity to iodine. People with known hypersensitivity to iodide should therefore avoid contact with the veterinary medicinal product.
Oral ingestion of this veterinary medicinal product can harm health. Drink plenty of water and seek medical advice immediately.
Keep away from food and animal feed.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Chronic exposure to iodine can lead to an iodine allergy (iodine eczema).
Allergic reactions to iodine can manifest as allergic skin reactions or, in rare cases, in the form of anaphylactic shock.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and/or lactation.

4.8 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.

4.9 Amounts to be administered and administration route

Teat use.
The solution should be administered undiluted by using the associated teat dip cup.
The cup should contain at least 5ml of the dipping solution. Dip the teats directly after milking and ensure that three quarters of the length of each teat are completely submerged in the solution. Refill the cup when required. The dip cup should be emptied after each milking and cleaned thoroughly before using again. This veterinary medicinal product is intended as a teat dip product for use after milking and can be used up to two times per day.
The duration of the application is unlimited.
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.

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

Not applicable.

4.11 Withdrawal period(s)

Meat and offal: zero days
Milk: zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals; antiseptics and disinfectants; iodine products
ATCvet code: QD08AG03

5.1 Pharmacodynamic properties

Free (molecular) iodine activity is based on a redox mechanism (the oxidising effect destroys micro-organisms) and the forming of salts with bacterial protein. The redox reaction involves various cell wall constituents, which are irreversibly transformed. It appears that sulfhydryl linkages, in bacterial cell wall components, are specifically affected by the iodine.
When used as an antiseptic, iodine solutions react with the organic matter of bacteria and viruses to render them harmless.
The product is an antiseptic. It has been demonstrated to be efficient against bacteria causing mastitis. It has been tested according to European Standards EN 1656 (field isolates) against *Escherichia coli*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* and *Streptococcus uberis*.

5.2 Pharmacokinetic particulars

Iodine interacts rapidly with any organic material after topical use, so that only little amounts of free iodine are adsorbed through the intact skin. In addition, only a small increase in serum iodine concentration is found after teat dipping.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol lauryl ether 9
Macrogol lauryl ether 2
C9-11 Pareth-6
Glycerol (85%)
Allantoin
Sodium acetate trihydrate
Potassium iodide
Purified water
(S)-Lactic acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)

6.2 Major incompatibilities

Alkalis and reducing substances

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

Do not store above 30°C and protect from frost.

6.5 Nature and composition of immediate packaging

Canister made of high density polyethylene (HDPE) containing 5kg (4.9 l), 10kg (9.7 l), 20kg (19.5 l) and 25kg (24.3 l) with HDPE closure caps with LDPE-foam sealing material
Canister made of HDPE containing 60 kg (58.4 l) with HDPE closure cap with EPDM sealing material
Drum made of HDPE containing 200kg (194.7l) with PP closure cap with PE sealing material and container made of HDPE containing 1000kg (973.2 l) with HDPE closure cap with PE-foam sealing material

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

F. Eimermacher GmbH & Co. KG
Westring 24
48356 Nordwalde
Germany

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD month YYYY}
{to be completed nationally}
Date of last renewal: {DD month YYYY}

10. DATE OF REVISION OF THE TEXT

{MM/YYYY} *{to be completed nationally}*

PROHIBITION ON SALE, SUPPLY AND/OR USE

{to be completed nationally}