

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

KENOSTART SPRAY AND DIP 3 mg/g Teat Dip or Spray Solution for cattle (dairy).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Available Iodine, 3 mg/g.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat Dip or Spray Solution.

Dark brown solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (dairy).

4.2 Indications for use, specifying the target species

Teat disinfection as part of a prevention strategy for mastitis in cattle.

4.3 Contraindications

Do not use in case 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.

Use for the treatment of teats with cutaneous lesions may delay wound-healing process. It is recommended to discontinue the treatment until the lesions are healed.

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

Avoid contact with eyes. If splashed in the eye, rinse with clean running water and seek medical advice.

In case of ingestion, drink large quantities of water and seek medical attention immediately.

Keep away from food and animal feed.

Wash hands after use.

When used as a spray, avoid working in the spray mist. Those who are hypersensitive to iodine should avoid using this product.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Repeated exposure to iodine can lead to iodine allergy. Allergic reactions to iodine may become apparent as allergic skin reaction but also as anaphylactic shock in rare cases.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other chemicals, teat disinfectants or teat care products.

4.9 Amounts to be administered and administration route

The product is suitable for dipping or spraying immediately after each milking. The veterinary medicinal product is supplied ready to use as a teat dip or spray. If a dip cup is used, it should hold at least 5 ml of veterinary medicinal product. Dip the teats immediately after milking each cow. Ensure that the teat is completely covered to three quarters of its length.

For the teat spraying, spray the entire surface of each teat with the veterinary medicinal product immediately after milking. The dip cup or sprayer should be replenished as necessary. The dip cup or sprayer should be emptied after milking and washed before reused. The product is meant to be used as a post-milking teat dip or spray up to two times per day.

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

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

4.11 Withdrawal Period(s)

Meat & offal: zero days

Milk: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotheapeutic group: Dermatologicals, antiseptic, disinfectant of iodine-based compound class
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 sulphhydryl 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 conditions) against *Staphylococcus aureus*, *Escherichia coli*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis* and *Corynebacterium bovis*,. These studies were carried out in 2005 at CIRLAM laboratory.

5.2 Pharmacokinetic properties

The published literature indicates that iodine coated onto the skin rapidly interacts with any organic material present leaving very little free iodine for absorption through the epidermis. It has also been reported that only a small increase in serum iodine concentration is found after teat dipping.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol 70%
Sodium hydrogen sulphite 40%
Ethoxylated Lanolin 50%
Sodium Iodate
Sodium Chloride
Sodium Hydroxide 30%
Sodium Iodide
Xanthan Gum
Alcohol (C12-C15) 11 Mole Ethoxylate
Citric Acid
Water Purified

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: 2 years

Shelf life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

Store in the original container

Keep the container tightly closed

Protect from frost

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

Protect from light

6.5 Nature and composition of immediate packaging

A dark brown liquid solution contained in 1, 5, 10, 20, 25, 60 litres, grey high-density polyethylene drums with HDPE caps and o-ring seals and 200 litres, in blue high-density polyethylene drums with HDPE caps and o-ring 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 product 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

CID LINES NV,
Waterpoortstraat, 2,
8900 IEPER,
BELGIUM.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10792/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27th January 2012

10 DATE OF REVISION OF THE TEXT