Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Kenostart 3 mg/g teat dip solution for cattle (dairy).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Available Iodine	3 mg/g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat Dip Solution.
Viscous 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 known hypersensitivity to iodine or any other excipients.

4.4 Special warnings for each target species

None.

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 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.
Iodine has an allergic potential. Persons with known iodine hypersensitivity must not handle the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used in lactating and pregnant cattle.

4.8 Interaction with other medicinal products and other forms of interaction

None known. Do not mix with other chemicals.

4.9 Amounts to be administered and administration route

The product is supplied ready to use as a teat dip. The dip cup should hold at least 5 ml of dip. Dip each teat immediately after milking. Ensure that the teat is completely covered to three quarters of its length. The Dip cup should be replenished as necessary. The dip cup should be emptied after treatment and washed before reuse. The product is meant to be used as a post-milking teat dip up to two times per day.

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 & offal: zero days
Milk: zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic 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 bacteria protein, the redox reaction involves various cell wall constituents, which are irreversibly transformed. It appears sulfhydryl linkages, in bacterial cell wall components, are specifically affected by the iodine.

KENOSTART has been demonstrated to be efficient against bacteria causing mastitis. It has been tested according to European Norms EN 1656 (field conditions) against *Staphylococcus aureus, Escherichia coli, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis* and *Corynebacterium bovis*. These studies were carried out in 2004 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 Bisulphite 40%
Ethoxylated Lanolin 50%
Sodium Iodate
Sodium Chloride
Sodium Hydroxide 30%
Sodium Iodide
Xanthan Gum
Alcohol (C13-C15) 11 Mole Ethoxylate
Fatty acid amide polyglycol ether
Citric Acid
Water Purified

6.2 Incompatibilities

As a general precaution, it is advisable not to mix the product with other chemicals. This veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary product as packaged for sale: 16 months
Shelf life after first opening the immediate packaging: To be used in the 6 months after first opening.

6.4 Special precautions for storage

Store upright in the tightly closed original container.
Protect from frost.
If the 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 liquid 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 is dangerous for aquatic organism.

7 MARKETING AUTHORISATION HOLDER

CID LINES NV
Waterpoortstraat, 2
8900 IEPER
BELGIUM

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10792/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th January 2011

10 DATE OF REVISION OF THE TEXT