SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the veterinary medicinal product:

For all CMS except France and Sweden
KENOSTART SPRAY AND DIP 3 mg/g Teat Dip or Spray Solution for cattle (dairy)

France
KENOSPRAY 3000, 3 mg/g Teat Dip or Spray Solution for cattle (dairy)

Sweden
Kenospray vet., 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 warning 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 5ml 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 periods:
Meat & offal: zero days
Milk: zero days

5. Pharmacological 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 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 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 particulars:
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 derived from the use of such products , if appropriate:
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

UK: VM 22136/4001
Transport emergency: For UK transport emergencies only phone 01865 407333

IE: VPA N° 10792/2/1
LM (Licensed Merchant)

9 Date of the first authorisation or date of renewal of the authorisation
06/09/2006

10 Date of revision of the text
14 March 2008