Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Kenocidin
Chlorhexidine digluconate 5 mg/ml, Teat dip solution for cattle (dairy)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:	
Chlorhexidine digluconate	5.00 mg
(Equivalent to chlorhexidine	2.815 mg)
Excipients:	
Patent Blue V (E131)	0.03 mg
Glycerol	51.00 mg
Allantoin	1.00 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat dip solution.
Blue viscous liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (dairy).

4.2 Indications for use, specifying the target species

Teat disinfection as a part of a prevention strategy for mastitis in lactating dairy cows.
For the maintenance of good teat skin and teat end condition.

4.3 Contraindications

Do not use in cases of known hypersensitivity to chlorhexidine or 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.
Allow product to dry before exposing the cows to wet (rainy), cold or windy conditions.
If the temperature is below freezing, allow teats to air dry before letting cows outside.
Use for the treatment of teats with cutaneous lesions may delay the wound healing process. It is recommended to discontinue the treatment until the lesions are healed. The presence of organic matter (pus, blood, etc.) may limit the action of the disinfectant chlorhexidine.
If signs of disease appear, consult a veterinary surgeon.

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 accidental ingestion, drink large quantities of water, seek medical advice immediately and show the package label to the physician.
Keep away from food and animal feed.
Wash hands after use.
People with known hypersensitivity to chlorhexidine should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Change of active ingredient teat dip type can on very rare occasions cause skin irritation.

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

Incompatibilities are mentioned in section 6.2

4.9 Amounts to be administered and administration route

The product is ready to use as a post-milking teat dip, applied up to two times per day.
Use at least 5ml per cow per application.
Dip the teats immediately after milking each cow. Ensure that the teat is completely covered to three quarters of its length.
The dip cup should be replenished as necessary.
If a common dip cup is used for application, a fresh solution should always be used at each milking. The dip cup should be emptied, cleaned and rinsed after each milking session or when the cup becomes contaminated during milking. Do not pour the remaining solution from the dip cup back into the original container. Do not use the product for cleaning and/or sanitizing milking equipment.

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 and Offal: Zero days.
Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, antiseptic, disinfectant based on chlorhexidine
ATCvet code: QD08AC02.

5.1 Pharmacodynamic properties

Chlorhexidine is a bisbiguanide antiseptic**.** Chlorhexidine has a broad-spectrum of activity. It is capable of rapidly and completely killing on contact practically all vegetative bacteria. Chlorhexidine has a mycostatic activity as well and prevents the out growth of bacterial spores.

Chlorhexidine causes cell wall disruption. This leads to modification, or loss, of permeability and damage. Leakage of intracellular constituents occurs as a consequence of cell death. Release of cell constituents occurs at very low concentrations. High concentrations of chlorhexidine cause coagulation of intracellular constituents. Due to electrostatic interaction with the acid phospholipids, the primary site of action is the cytoplasmic membrane.

All species of vegetative bacteria are susceptible to this action of chlorhexidine and there is no documented resistance mechanism in the field.

Chlorhexidine is an antiseptic. The product has been tested according to European Standards EN 1656 (field conditions) against *Staphylococcus aureus, Pseudomonas aeruginosa, Proteus vulgaris, Enterococcus hirae, E. coli, S. agalactiae, S. dysgalactiae, S. uberis, Corynebacterium bovis, Streptococcus bovis, Klebsiella, Citrobacter, Enterobacter*.

5.2 Pharmacokinetic properties

Chlorhexidine is not significantly absorbed through the skin after topical application and therefore no systemic pharmacokinetic activity is indicated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Glycerol
Allantoin
Isopropyl alcohol
Macrogol stearate
Guar
Mint oil, partly dementholised
Citric acid monohydrate
Sodium hydroxide 30% solution
Water, purified

6.2 Incompatibilities

Chlorhexidine can be inactivated by anionic and nonionic surfactants (eg soaps, even natural) or inorganic anions, so do not mix with tap water, other chemicals, disinfectants and other products for the teat and udder care.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

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

1 litre white high-density polyethylene multidose containers (HDPE) with HDPE screw-caps and o-ring seals.
5, 10, 20, 25, 60 and 200* litre, blue HDPE multidose containers with HDPE screw-caps and o-ring seals. The overseal on the 200 litres presentation is red.
Not all pack sizes may be marketed.
* The 200 litre multidose container should not be returned for re-filling.

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.
HARMFUL TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used container.

7 MARKETING AUTHORISATION HOLDER

CIDLINES NV
Waterpoortstraat 2
8900 Ieper
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10792/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st April 2011
Date of last renewal: 17th April 2015

10 DATE OF REVISION OF THE TEXT