SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

For all CMSs except Spain
Kenocidin
Chlorhexidine digluconate 5mg/g, Teat dip solution for cattle (dairy)

For Spain
Kenocidin
5mg/g, Teat dip solution for cattle (dairy)
Chlorhexidine digluconate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active substance:	
Chlorhexidine digluconate	5.0 mg/g
(Equivalent to chlorhexidine	2.815 mg/g)
Excipients:	
Patent Blue V (E131)	0.03 mg/g
Other Constituents:	
Glycerol	51 mg/g
Allantoin	1 mg/g

For a 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 case 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

i. 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.

ii. Special precautions for 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.
People with known hypersensitivity to chlorhexidine should avoid contact with the veterinary medicinal product.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

None known

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

None known.

4.9 Amount(s) 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 PROPERTIES

Pharmacotherapeutic group:

Dermatologicals, antiseptic, disinfectant based on chlorhexidine

ATC Vet 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. KENOCIDIN 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 particulars

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 Hydroxyde 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 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 product 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 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.

UK Only: To dispose of unused product to land you must have an authorisation under the Groundwater Regulations 1998.

7 MARKETING AUTHORISATION HOLDER

CIDLINES NV
Waterpoortstraat 2
8900 Ieper
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION

Date:

10. DATE OF REVISION OF THE TEXT

Date: