SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:	
Chlorhexidine digluconate	5.00 mg
(Equivalent to chlorhexidine	2.815 mg)
Excipients:	
Brilliant Blue 85% (E133)	0.035 mg
Glycerol	60.00 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

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 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

Brilliant Blue 85% (E133)
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 product or waste materials derived from the use of such products

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.

UK only: To dispose of unused product to land you must have an authorisation under the groundwater regulations currently in force.

7. MARKETING AUTHORISATION HOLDER

CIDLINES NV
Waterpoortstraat 2
8900 Ieper
Belgium
Tel. +32 (0) 57 21 78 77
Fax. +32 (0) 57 21 78 79
Mail: info@cidlines.com

8. MARKETING AUTHORISATION NUMBER(S)

Vm 22136/4002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 November 2009
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Chlorhexidine digluconate: 5.00 mg/ml (Equivalent to chlorhexidine 2.815 mg/ml)
Patent blue V (E131): 0.03 mg/ml
Glycerol: 51.00 mg/ml
Allantoin: 1.00 mg/ml

3. PHARMACEUTICAL FORM

Teat Dip Solution
Blue Viscous Liquid

4. PACKAGE SIZE

1L, 5L,10L, 20L, 25L, 60L, 200L. Not all pack sizes may be marketed.

5. TARGET SPECIES

Cattle (dairy).

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Teat use.
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.

8. WITHDRAWAL PERIOD

Meat & offal: zero days
Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Ensure udder and teats are clean and dry before the next milking.
Can be used during pregnancy and lactation.
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
This veterinary medicinal product is for teat use, significant absorption does not occur.

- **Special precautions for use in animals**

For external use only.
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 the temperature is below freezing, allow teats to air dry before letting cows outside
If signs of disease appear, consult a veterinary surgeon
Allow product to dry before exposing the cows to wet (rainy), cold or windy conditions.

- **Operator Warnings**

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.

- **Adverse reactions**

Change of active ingredient teat dip type can on very rare occasions cause skin irritation.
If you notice any serious effects or other effects not mentioned in this package label, please inform your veterinary surgeon.

- **Contraindicatons**

Do not use in cases of known hypersensitivity to chlorhexidine or any of the excipients.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 6months.

Discard date:____/_____/_____

11. SPECIAL STORAGE CONDITIONS

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
Do not use after the expiry date stated on the label
The 200 litre container should not be returned for re-filling

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

UK only: To dispose of unused product to land you must have an authorisation under the groundwater regulations currently in force.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Name and address of the marketing authorisation holder and manufacturing authorisation holder responsible for batch release:
CIDLINES NV
Waterpoortstraat 2
8900 Ieper
Belgium
Tel. +32 (0) 57 21 78 77
Fax. +32 (0) 57 21 78 79
Mail: info@cidlines.com

16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 22136/4002 - For UK transport emergencies only phone 01865407333
IE: VPA number: 10792/003/001

17. MANUFACTURER'S BATCH NUMBER

Lot