

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Kenocidin SPRAY AND DIP

Chlorhexidine digluconate 5 mg/ml, Teat Dip / Teat Spray 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	60.00 mg
Allantoin	1.00 mg

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Teat Dip / Teat Spray Solution.

Blue Liquid Solution.

### 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

If signs of disease appear, or persist, consult a veterinary surgeon.

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.

### 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 and seek medical attention immediately.

Keep away from food and animal feed.

Wash hands after use.

When the product is used as a spray, avoid working in spray mist.

People with known hypersensitivity to chlorhexidine should avoid contact with the 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 or spray, applied up to two times per day.

Use at least 5 ml 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. Alternatively, spray the entire surface of each teat immediately after milking.

The dip cup or sprayer should be replenished as necessary.

If a common dip cup or sprayer is used for application, a fresh solution should always be used at each milking. The dip cup or sprayer should be emptied, cleaned and rinsed after each milking session or when the cup or sprayer becomes contaminated during milking. Do not pour the remaining solution from the dip cup or sprayer 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 efficacy. 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.

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  
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 and drums with HDPE screw caps and o-ring seals.

The overseal on the 200 litre presentation is red.

Not all pack sizes may be marketed.

\* The 200 litre 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 10792/004/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15<sup>th</sup> July 2011

Date of last renewal: 24<sup>th</sup> April 2015

## **10 DATE OF REVISION OF THE TEXT**