

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Helodip 3.1 % w/v Teat Dip Concentrate

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### Active Substance

Ammonium Lauryl Sulphate	3.1	% w/v
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### Excipients

Sodium Methyl Parahydroxybenzoic acid	0.3	% w/v
Quinoline yellow (E104)	0.02	% w/v

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Teat dip concentrate.

A clear, faintly opalescent, yellow slightly viscous solution.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle.

### 4.2 Indications for use, specifying the target species

To reduce the incidence of mastitis in lactating cows and heifers. Also, to maintain the skin condition of the udder.

### 4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

#### Special precautions for use in animals

None.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with eyes. If splashed into the eye, irrigate with copious amounts of water.

### 4.6 Adverse reactions (frequency and seriousness)

None known.

### 4.7 Use during pregnancy, lactation or lay

Helodip may be used in pregnant and lactating animals.

#### **4.8 Interaction with other medicinal products and other forms of interactions**

None known.

#### **4.9 Amounts to be administered and administration route**

Add 3 parts clean water to 1 part Helodip.

Apply the solution on the teats by dipping cup or modern sprayer. Animals must be treated immediately after milking.

Change solution and wash dipping cup regularly.

Helodip can also be used as a pre-milking dip. Wash teats clean with water, dip teats and after 30 seconds dry off dip with paper towels and proceed with milking.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Not applicable.

#### **4.11 Withdrawal period(s)**

Meat and offal: Zero days

Milk: Zero hours

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiseptics and disinfectants, ammonium lauryl sulphate.

ATCvet code: QD08AX

#### **5.1 Pharmacodynamic properties**

Helodip acts by firstly ensuring a total bacteriocidal effect on mastitis-causing organisms on the skin. It maintains effective control against bacteria during the critical periods of exposure between milkings.

Helodip also possesses enhanced skin conditioning properties, which assist in the maintenance of good skin condition. This in itself ensures a reduction in the number of bacteria capable of surviving on the teats.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Glycerol

Urea

Lactic Acid

Whey powder

Povidone K90

Sodium Methyl Parahydroxybenzoic Acid

Sorbic acid

Antifoam PD 30

Quinoline Yellow (E104)

Purified Water

#### **6.2 Major incompatibilities**

None known.

#### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after dilution according to directions: 24 hours.

#### **6.4 Special precautions for storage**

Do not store above 25°C.

#### **6.5 Nature and composition of immediate packaging**

5L and 20L white high density polyethylene container with tamper evident lids.  
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**

Unused product should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

### **7 MARKETING AUTHORISATION HOLDER**

Bimeda Animal Health Limited  
2, 3 & 4 Airton Close  
Airton Road  
Tallaght  
Dublin 24  
Ireland

### **8 MARKETING AUTHORISATION NUMBER(S)**

VPA22033/024/001

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

Date of first authorisation: 20 June 1994  
Date of last renewal: 19 June 2009

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

May 2019