

**IRISH MEDICINES BOARD ACT 1995**

**EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007**

**(S.I. No. 786 of 2007)**

VPA: **10959/009/001**

Case No: 7005498

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

**Bimeda Holdings PLC**

**Broomhill Road, Tallaght, Dublin 24, Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Helodip 3.1 % w/v Teat Dip Concentrate**

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **19/06/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

## Part II

### 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
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Quinoline yellow (E104)	0.02 % w/v
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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 interaction

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 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

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

## 7 MARKETING AUTHORISATION HOLDER

Bimeda Holdings Plc,  
Broomhill Road,  
Tallaght,  
Dublin 24.

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10959/009/001

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

19<sup>th</sup> June 2009

**10 DATE OF REVISION OF THE TEXT**