**IRISH MEDICINES BOARD ACT 1995**

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

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

VPA: **10837/001/001**
Case No: 7004238

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:

**G.A.M.**

**IDA East Industrial Estate**, **Pulleen**, **Co. Cork**, **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:

**Hexidip Chlorhexidine Digluconate 0.425% Teat Dip**

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 revoked, shall continue in force from **11/03/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: 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

Hexidip Chlorhexidine Digluconate 0.425% Teat Dip Solution.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | |
|---|---|
| Active substance: | |
| Chlorhexidine digluconate | 0.425 % w/v |
| (As Chlorhexidine Digluconate Solution) | |
| Excipient: | |
| Ponceau 4R (E124) | 0.001 % w/v |

For a full list of the excipients, see Section 6.1.

## 3 PHARMACEUTICAL FORM

Pink-red pearlescent teat dip solution.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dairy cows.

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

Dairy cows: For routine use as an aid in the control of bovine mastitis.

### 4.3 Contraindications

Do not use in animals with known hypersensitivity to the constituents of the product.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

**Special precautions for use in animals**
Avoid contact with the eyes.

Before milking, teats should be washed and thoroughly dried, preferably with an individual paper towel.

**Special precautions to be taken by the person administering the medicinal product to animals**
In case of contact with eyes give prolonged irrigation with water and obtain medical advice. Avoid working in spray mist.
In case of ingestion medical attention should be sought as soon as possible.

## 4.6 Adverse reactions (frequency and seriousness)

Skin sensitivity to chlorhexidine has occasionally been reported.

## 4.7 Use during pregnancy, lactation or lay

The product is intended for use during pregnancy and lactation.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

For teat use.

Udder washing:

Wash and dry the udder before milking. Dilute 85 ml (3 fl.oz) in 4.5 litres (1 gallon) of water. A fresh solution should be prepared daily. Use disposable paper towels instead of cloths.

Teat dipping:

Fill dipping cup two-thirds full.
Dip the full length of each teat after milking.
Refill the dipping cup as necessary.
Discard all used dip at the end of each milking.

Teat Spraying:

Immediately after milking, spray the entire surface of each teat.

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

Not applicable.

## 4.11 Withdrawal Period(s)

Zero days. No withdrawal period is required before slaughtering or milk production for human consumption.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code; QD08AC02
Pharmacotherapeutic Group: Antiseptics and disinfectants.

Chlorhexidine is a wide spectrum bactericide which is effective against common mastitis causing bacteria.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol
PEG-75 Lanolin
Peppermint Oil
Ponceau 4R (E124)
Vinyl pyrollidone styrene copolymer emulsion
Hydrogenated Polyoxyl Castor Oil
Purified Water

### 6.2 Incompatibilities

Chlorhexidine salts are incompatible with soaps and other anionic materials.

### 6.3 Shelf-life

Shelf life of the veterinary medicinal preparation as packaged for sale: 2 years.

### 6.4 Special precautions for storage

Do not store above 25°C.

### 6.5 Nature and composition of immediate packaging

5, 10, 20, and 25 litre HDPE bottle with EPE cap liner and PP/PE cap.
200 litre HDPE bottle with EPDM gasket and PP bung.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Hexidip should not enter water courses as this may be dangerous for fish and other aquatic organisms.

## 7 MARKETING AUTHORISATION HOLDER

G.A.M. Limited
Pulleen
Kanturk
Co. Cork

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10837/1/1

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

20th December 2000/20th December 2005

## 10 DATE OF REVISION OF THE TEXT

11th March 2008