

**IRISH MEDICINES BOARD ACT 1995**

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

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

VPA: **10908/001/001**  
Case No: 7004720

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:

**DeLaval Ireland Ltd**

**Unit 6, Shamrock Business Park, 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:

**Dipal Concentrate Teat Dip/Teat Spray Solution**

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 **26/10/2008**.

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

Dipal Concentrate  
Teat Dip/Teat Spray Solution

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active substance:

Concentrate: macrogol lauryl ether/iodine complex providing 2 % w/v available iodine.  
Ready-to-use solution (1+3): 0.5% w/v available iodine

##### Excipients:

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Concentrate for teat dip/teat spray solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Dairy cattle.

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

As an aid in the prevention of mastitis in lactating cattle.

##### 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 precaution(s) for use in animals

For external use only.

Dipping: Dip the full length of the teats.

Spraying: Spray the full length of the teats.

After completion of milking discard remaining solution from the teat dip cup. Wash out the teat cup before re-use.

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

In case of ingestion, obtain medicinal attention as soon as possible.

In case of contact with eyes, rinse immediately with water and seek medical advice.

Wear goggles when diluting Dipal Conc.

Wash hands after use.

Avoid working in spray mist.

## 4.6 Adverse reactions (frequency and seriousness)

None known.

## 4.7 Use during pregnancy, lactation or lay

This product may be given to 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

### For topical administration to the teats.

Use Dipal Conc. diluted immediately after milking.

Wipe the teats with a wet or dry paper towel before milking.

Strip milk into the fore milk cup.

Milk as usual. Dip or spray the teats with Dipal after each milking. Spray the entire surface or dip the full length of each teat.

### Dosage

1 part of Dipal Conc. in 3 parts of water, or pour 50 ml Dipal Conc. in the Alfa-Laval dip cup and fill with water to 200 ml.

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

Not applicable.

## 4.11 Withdrawal Period(s)

Nil - in order to avoid iodine residues in milk, it is important to clean teats before milking and discard fore milk.

Nil withdrawal period for slaughter of treated animals.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiseptics and disinfectants, Iodine products  
ATCvet Code: QD08AG

### 5.1 Pharmacodynamic properties

Dipal Conc is an antiseptic. The active form of this product is the free (molecular) iodine. It's activity is based on a redox mechanism (the oxidising effect burns up micro-organisms) and the forming of salts with bacterial protein.

When used as an antiseptic, iodine solutions react with the organic matter of bacteria and viruses to render them harmless. The mechanism of kill appears to be due to an oxidative-reductive reaction, involving various cell wall constituents, which are irreversibly transformed. It appears sulfhydryl linkages, in bacteria cell wall components, are specifically targeted by the iodine.

### 5.2 Pharmacokinetic properties

Literature suggests that absorption of iodine through the skin is well below levels which would have pharmacokinetic activity.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol  
Sorbitol  
Purified Water

### 6.2 Incompatibilities

Do not mix with any other medicinal products.

### 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year.  
Shelf-life after dilution according to directions: 28 days.

### 6.4 Special precautions for storage

Do not store above 25°C.  
Store in the original can.  
Keep the can tightly closed.  
Store away from food, drink and animal foodstuffs.

### 6.5 Nature and composition of immediate packaging

Polyethylene containers of 5, 10, 20, 25, 60 or 200 litre closed with polyethylene cap and safety-sealing ring.  
Not all pack sizes may be marketed.

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

Harmful to fish - do not contaminate ponds, waterways and ditches with the product or empty container.

Wash out empty container thoroughly and dispose of safely.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

DeLaval Ireland Ltd.,  
Unit 6,  
Shamrock Business Park,  
Carlow  
Ireland.

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

VPA 10908/001/001

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

26th October 2008

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