**IRISH MEDICINES BOARD ACT 1995**

**MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998**

**(S.I. No.142 of 1998)**

**PA0979/018/001**
Case No: 2032524

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Reckitt Benckiser Ireland Ltd**

**7 Riverwalk**, **Citywest Business Campus**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Dettol Antiseptic Pain Relief Spray**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **06/02/2007** until **09/12/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Dettol Antiseptic Pain Relief Spray.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | | |
|---|---|---|
| Lidocaine hydrochloride | 2.2 | % w/v |
| Benzalkonium chloride (50% solution) | 0.395 | % w/v |

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous spray, solution.

Clear colourless liquid with characteristic odour.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the antiseptic cleansing and pain relief of minor wounds such as cuts and skin grazes, insect bites and stings, small burns and scalds.

### 4.2 Posology and method of administration

For adults and children: Spray the affected area as needed and wipe away any excess liquid with clean tissue or cotton wool. Repeat as necessary.

### 4.3 Contraindications

None known.

### 4.4 Special warnings and precautions for use

Label warning: For external use only. Do not use around the eyes or ears, in the mouth or over large areas of the body. Do not inhale. In the case of accidental eye contact, the eyes should be irrigated with copious amounts of cold water.

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

None known.

### 4.6 Pregnancy and lactation

There is no direct evidence on the use of lidocaine hydrochloride in human pregnancy, but it has been in wide use for many years without apparent ill consequence. As with all medicines, the use of Dettol Antiseptic Pain Relief Spray is contraindicated in early pregnancy unless absolutely essential.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

None known.

## 4.9 Overdose

Not applicable.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

5.1.1. Benzalkonium chloride

Benzalkonium chloride is a quaternary ammonium compound which has been used for many years as a surfactant and antiseptic/ disinfectant. It is known to be bactericidal in low concentrations to a wide range of Gram positive and Gram negative bacteria.

5.1.2. Lidocaine hydrochloride

Lidocaine hydrochloride is an established local anaesthetic agent which produces tissue insensitivity by virtue of its ability to impede the inward flux of sodium ions, thus preventing transmission of the nerve impulse.

## 5.2 Pharmacokinetic properties

5.2.1. Benzalkonium chloride

Quaternary ammonium compounds such as benzalkonium chloride are only absorbed to a very small extent through human skin.

5.2.2. Lidocaine hydrochloride

Lidocaine hydrochloride is only very slowly absorbed from intact skin as it is not lipophilic.

## 5.3 Preclinical safety data

5.3.1. Benzalkonium chloride

The low level of benzalkonium chloride in the product, coupled with its low level absorption from intact and broken skin, make it unlikely that any significant systemic toxic effect should arise from its use. There is evidence that it can have an irritant effect on mucous membranes.

5.3.2. Lidocaine hydrochloride

The low level of lidocaine hydrochloride in the product and amount applied to the skin make it unlikely that any systemic toxic effect would arise from its use.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Propylene glycol
Sodium dihydrogen phosphate dihydrate
Sodium phosphate
Jumble 2G perfume
Disodium edetate
Purified water.

## 6.2 Incompatibilities

Benzalkonium chloride may be deactivated when used with soap or other surfactants.

## 6.3 Shelf Life

Three years.

## 6.4 Special precautions for storage

None.

## 6.5 Nature and contents of container

White HDPE container with a spray pump. The pump head is protected by a clear, polypropylene co-polymer overcap. The pack size is 50 ml.

## 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

# 7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

# 8 MARKETING AUTHORISATION NUMBER

PA 979/18/1

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th December 1998
Date of last renewal: 10th December 2003

# 10 DATE OF REVISION OF THE TEXT

February 2007