IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0979/005/001
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 Fresh 4% w/v Concentrate for Cutaneous Solution

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 **24/11/2007**.

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 Fresh 4 %w/v Concentrate for Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzalkonium chloride 4.0 %w/v.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Concentrate for Cutaneous solution
A clear, colourless concentrate for cutaneous solution with a characteristic lemon/pine odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic for prophylaxis of topical infection in intact and abraded skin and for skin preparation prior to surgical or diagnostic procedure.

4.2 Posology and method of administration

Route of administration – topical to relevant areas.

Dilutions for use – application as required:

1. Wound cleansing and disinfection

5% (1 in 20). 50 ml to one litre, one tablespoon to half a pint. Abrasions, bathing and irrigation of wounds, cuts and bites, spots and pimples (not eczematous conditions).

2. External antisepsis

2.5% (1 in 40). 25 ml to one litre, one tablespoon to one pint. Routine use in obstetrics and midwifery.

4.3 Contraindications

Use in patients hypersensitive to the active ingredient.

Use when bathing infants up to nine months old.

4.4 Special warnings and precautions for use

Label warnings

For external use only.

If swallowed, wash out mouth and drink plenty of water or milk. If contact is made with eyes, wash thoroughly with cold water.

In both cases, consult your doctor and take this bottle with you.

If the condition persists or is aggravated, discontinue use and consult the doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Not applicable.

4.9 Overdose

In the event of accidental ingestion of small quantities of Dettol Fresh, transient emetic and purgative effects may occur for which the recommended treatment is the administration of a demulcent (e.g. milk).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzalkonium chloride is a quaternary ammonium compound which has been used for many years as a surfactant and antiseptic/disinfectant.

5.2 Pharmacokinetic properties

Quaternary ammonium compounds such as benzalkonium chloride are only absorbed to a very small extent through human skin and therefore pharmacokinetic studies have not been carried out.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Propylene glycol
Isopropyl alcohol
Perfume fresh
Water

6.2 Incompatibilities

Dettol Fresh is incompatible with soaps and other anionic surfactants.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Green tinted PVC bottle with a polypropylene screw cap with a polyethylene or PVDC wad.
Pack sizes: 125 ml, 250 ml, 500 ml and 750 ml.

Not all pack sizes may be marketed.

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 979/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 November 1992

Date of last renewal: 25 November 2002

10 DATE OF REVISION OF THE TEXT

February 2007