IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0979/044/001
Case No: 2084633

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

Itch Relief Cream Lauromacrogols 3.0% w/w Urea 5.0% w/w

the particulars of which are set out in 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 **27/08/2010**.

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

Itch Relief Cream
Lauromacrogols 3.0 % w/w
Urea 5.0 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	Percentage (w/w)
Lauromacrogols	3.0 %
Urea	5.0 %

For excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A white smooth cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of pruritus, eczema, dermatitis, and scaling skin conditions where an antipruritic and/or hydrating effect is required. It may also be used for the continued treatment and follow-up treatment of these skin diseases.

4.2 Posology and method of administration

Adults, the elderly and children: Itch Relief Cream should be applied to each affected area twice a day. The duration of treatment depends on the clinical response. For external use only.

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients. It should not be used to treat acute erythroderma, acute inflammatory, oozing or infected skin lesions.

4.4 Special warnings and precautions for use

Itch Relief Cream may cause irritation if applied to broken or inflamed skin.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

For Itch Relief Cream no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

There are no specific restrictions concerning its use during pregnancy, but it is not to be used on the breasts immediately prior to breast feeding during lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Itch Relief Cream has been reported to cause a burning sensation, erythema, pruritus or the formation of pustules, aggravation of eczema if applied to inflamed skin areas. Contact allergy has also been reported.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antipruritics incl. antihistamines, anaesthetics etc.
ATC code: D 04 AX

Urea is a physiological product derived from human protein metabolism. It is found naturally in the skin and when applied topically it can increase the horny layer's capacity to retain water. Itch Relief Cream has been shown to increase skin hydration and when used as recommended provides hydration for 24 hours.

Patients with eczema and psoriasis have been shown to have decreased levels of urea in their skin. Urea is not allergenic and is well-tolerated at a concentration of 5%.

Lauromacrogols have the properties of a topical anaesthetic and have an antipruritic effect. The local tolerability of lauromacrogols is good.

Itch Relief Cream has also been shown to increase the lipid content of the epidermis thus soothing and smoothing the skin.

After twice-daily application for 4 weeks to non-infected eczematous lesions, in addition to an improvement in the clinical condition, use of Itch Relief Cream was associated with a significant reduction in total bacteria and Staph. aureus counts. A reduction in Staph. aureus count ($p \leq 0.01$) was observed on eczematous skin from Day 1 (148 organisms/cm^2) to Day 29 (11.8 organisms/cm^2). However, no bactericidal or bacteriostatic effects have been tested for.

5.2 Pharmacokinetic properties

Little urea is absorbed after topical application. It is mainly excreted in the urine, and to a lesser extent in perspiration.

There is no evidence of systemic availability of lauromacrogols after topical administration.

5.3 Preclinical safety data

No specific studies have been performed with Itch Relief Cream. Urea and lauromacrogols have been used therapeutically for many years in humans. Information from animal studies are unlikely to provide any further relevant information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethicone
Phenyl dimeticone
Liquid paraffin
Cetyl palmitate
Stearic palmitic acid
Octyldodecanol
Glycerol 85%
Polysorbate
Carbomer
Trometamol
Benzyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tubes with double internal lacquer of epoxy phenol resin and closure made of polyethylene. Content: 10 g, 35 g, 50 g, 75 g and 100 g.

Plastic pump dispensers. Content: 175 g, 180 g, 185 g, 190 g, 200 g and 500 g.

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

8 MARKETING AUTHORISATION NUMBER

PA 979/44/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th May 2003
Date of last renewal: 20th January 2007

10 DATE OF REVISION OF THE TEXT

September 2009