

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0823/016/002

Case No: 2050321

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

McNeil Healthcare (Ireland) Ltd

Airton Road, Tallaght, Dublin 24, Ireland

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

Benadryl Skin Allergy Relief Lotion

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 **21/05/2008** until **31/03/2009**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benadryl Skin Allergy Relief Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benadryl Skin Allergy Relief Lotion contains:

Diphenhydramine hydrochloride	1	% w/v
Zinc oxide	8	% w/v
Racemic camphor	0.1	% w/v

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous liquid

A smooth, pink viscous cutaneous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Benadryl Skin Allergy Relief Lotion is indicated in the topical treatment of skin manifestations of allergy (e.g., urticaria and hives), and for the relief of irritation associated with shingles, sunburn, prickly heat and other minor skin affections.

4.2 Posology and method of administration

Adults:

Topical. Benadryl Skin Allergy Relief Lotion may be applied to affected parts, three to four times daily.

Children and Infants:

Topical. As for adults.

The Elderly:

Topical. As for adults.

4.3 Contraindications

Do not use on chicken pox or measles or exudative dermatoses, unless supervised by a doctor.

Do not use on extensive areas of the skin except as directed by a doctor.

Do not use any other drugs containing diphenhydramine whilst using this product.

4.4 Special warnings and precautions for use

Benadryl Skin Allergy Relief Lotion should not be applied to raw, or broken surfaces or mucous membranes as this may result in percutaneous absorption giving rise to systemic effects. Avoid contact with the eyes. If a burning sensation or rash develops or if the condition persists, treatment should be discontinued. If necessary remove by

washing with soap and water.

The pack labelling contains the following warnings:

Do not apply to raw surfaces.

If a burning sensation or rash develops, or if symptoms persist, consult the doctor.

Do not use on chicken pox, measles or large areas of skin unless directed by a doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

The safety of Benadryl Skin Allergy Relief Lotion in pregnancy and lactation has not been established. Like any medicine, Benadryl Skin Allergy Relief Lotion should only be used if the possible benefits outweigh the potential risks involved. Diphenhydramine is known to be absorbed through the skin. Diphenhydramine crosses the placental barrier and is secreted in breast milk.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely, skin sensitization, eczematous reactions and photosensitivity have been reported after topical application of antihistamines. If this occurs, treatment should be discontinued.

4.9 Overdose

Symptoms and signs

Accidental ingestion or excessive absorption of Benadryl Skin Allergy Relief Lotion may lead to dose-related signs of diphenhydramine toxicity. These include drowsiness and sedation with anticholinergic symptoms prevailing. Camphor may produce nausea, vomiting and dizziness. At higher doses, delirium leading to coma, ataxia, increased muscle reflexes and cloniform convulsions may appear.

Treatment

The stomach should be emptied by lavage and aspiration. In cases of acute poisoning, activated charcoal may be useful. A sodium sulphate purgative may be given. Convulsions may be controlled by diazepam or thiopental sodium. In the case of camphor poisoning, lipid haemodialysis or resin haemoperfusion may be useful.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benadryl Skin Allergy Relief Lotion contains diphenhydramine hydrochloride, zinc oxide and camphor. Diphenhydramine is a powerful antihistamine and local anaesthetic (antipruritic). In concentrations of between 0.1 - 3.0 %, camphor depresses cutaneous receptors and is an effective analgesic, anaesthetic and antipruritic, which provides a feeling of coolness when applied topically.

5.2 Pharmacokinetic properties

Benadryl Skin Allergy Relief Lotion is intended only for topical application to the skin. At the recommended dose little

of the active ingredients will be absorbed. Percutaneous penetration of diphenhydramine and camphor has been demonstrated during inappropriate use of these compounds separately, but has not been quantified.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ferric oxide red (E172)
Ferric oxide yellow (E172)
Carmellose sodium
Glycerol
Perfume oil soleil 78087
Hydrochloride
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.
Store in original package.

6.5 Nature and contents of container

Benadryl Skin Allergy Relief Lotion is stored in a 125 ml round amber bottle with a 28 mm roll-on-pilfer-proof (ROPP) aluminium cap or with a 3 piece plastic child resistant, tamper evident closure fitted with a polyester faced wad.

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

McNeil Healthcare (Ireland) Ltd
Airton Road
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 823/16/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1979

Date of last renewal: 01 April 2004

10 DATE OF REVISION OF THE TEXT

May 2008