

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Benadryl Skin Allergy Relief Cream  
Diphenhydramine hydrochloride 1.0% w/w  
Zinc Oxide 8.0% w/w  
Racemic Camphor 0.1% w/w

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benadryl Skin Allergy Relief Cream contains:

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

The cream also contains:

Cetostearyl Alcohol	8.9	% w/w
Propyl Parahydroxybenzoate (E216)	0.2	% w/w
Propylene Glycol	10	% w/w

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cream  
A smooth, pink cream.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Benadryl Skin Allergy Relief Cream 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 Cream 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 Cream 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 Fertility, pregnancy and lactation

The safety of Benadryl Skin Allergy Relief Cream in pregnancy and lactation has not been established. Like any medicine, Benadryl Skin Allergy Relief Cream 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 Cream 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 Cream 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 Cream 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)  
White ceresin  
Cetostearyl alcohol  
Perfume oil soleil 78087  
Sorbitan stearate  
Propyl Parahydroxybenzoate (E216)  
Propylene glycol  
Polysorbate 60  
Purified water

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

Do not store above 25°C.  
Store in original package.

## **6.5 Nature and contents of container**

Benadryl Skin Allergy Relief Cream is stored in a 42 g epoxy phenolic-based lacquered aluminium tube. Tubes are closed by a white spiked screw cap made of polypropylene.

## **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 823/16/1

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

Date of first authorisation: 01 April 1979

Date of last renewal: 01 April 2009

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

June 2009