

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisyl Skin Cream 1%

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone (micronized) 1% w/w.

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Cream

A smooth white uniform cream.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

As a prescription only medicine:

In the management of corticosteroid-sensitive superficial dermatoses.

As a pharmacy medicine:

External: Use only for contact dermatitis, irritant dermatitis and insect bite reactions.

Route:

Topical.

### 4.2 Posology and method of administration

Adults & Children:

Apply one to four times daily, or as directed by a physician. Once improvement is evident frequency of application should be gradually reduced.

Do not use on children under 12 years of age without medical supervision. In this group, this product should be applied sparingly over a small area once or twice a day for a maximum of one week.

### 4.3 Contraindications

1. Use in the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.
2. Use in acne rosacea or in perioral dermatoses.
3. Use in plaque psoriasis.
4. Not for use on the eye, face, in the anogenital region, on broken or infected skin, including cold sores, acne and athletes foot.

5. Hypersensitivity to active ingredient or to excipients.

#### 4.4 Special warnings and precautions for use

1. Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of the possibility of adrenocortical suppression and growth retardation.
2. Prolonged use of uninterrupted occlusion (including napkins) or use with extensive occlusive dressings may suppress adrenocortical function.
3. Continuous application without interruption will result in local atrophy of the skin, striae, and superficial vascular dilatation, particularly on the face.
4. Prolonged use in the management of acne vulgaris should be avoided.
5. Use in psoriasis may lead to generalisation, excessive systemic absorption and rebound relapse on cessation of use.
6. Pheochromocytoma crisis, which can be fatal, has been reported after administration of corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation (see section 4.8)
7. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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

None known.

#### 4.6 Fertility, pregnancy and lactation

Animal studies have shown teratogenic effects. To date similar effects have not been shown in man. This product should not be used in pregnancy or lactation unless considered essential by the physician.

#### 4.7 Effects on ability to drive and use machines

None.

#### 4.8 Undesirable effects

Striae may occur especially in intertriginous areas.

##### Skin and subcutaneous disorders:

Frequency not known: Urticaria

##### Endocrine disorders:

Frequency not known: Pheochromocytoma crisis

##### Eye disorders:

Vision blurred (see also section 4.4).

### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

## **4.9 Overdose**

Not applicable.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

ATC code: D07AA02

Hydrocortisone is an anti-inflammatory steroid.

## **5.2 Pharmacokinetic properties**

The literature states that absorption does occur through the skin, particularly denuded skin. However, this absorption is not of clinical significance as hydrocortisone topically has only rarely been associated with side effects resulting from pituitary-adrenal suppression.

## **5.3 Preclinical safety data**

Not applicable.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Cetomacrogol emulsifying wax

Chlorocresol

Liquid paraffin

Macrogol 300

White soft paraffin

Purified water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

Unopened: 3 years.

In-use shelf life – 4 weeks after first opening.

## **6.4 Special precautions for storage**

Do not store above 25°C.

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

Hydrocortisyl Skin Cream is available in collapsible aluminium tubes in packs of 5, 10, 15, 20 and 30g.

Tube caps are made from opaque high density polyethylene.

## **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**

Sanofi-Aventis Ireland Ltd. T/A SANOFI  
Citywest Business Campus  
Dublin 24  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA0540/046/001

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

Date of first authorisation: 01 April 1978

Date of last renewal: 25 November 2004

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

June 2017