

# 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:

This medicinal product is indicated in the management of corticosteroid-sensitive superficial dermatoses.

As a pharmacy medicine:

This medicinal product is indicated for 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 two times daily, or as directed by a physician. Once improvement is evident frequency of application should be gradually reduced.

Hydrocortisyl should not be used 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. Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1
2. In the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.
3. In acne rosacea or in perioral dermatoses
4. In plaque psoriasis
5. Not for use on the eye, face, in the anogenital region, on broken or infected skin, including cold sores, acne and athlete's foot.

### 4.4 Special warnings and precautions for use

Hydrocortisyl is for external use only. Do not apply to mucosal surfaces. Avoid contact with eyes.

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.

Prolonged use of uninterrupted occlusion (including napkins) or use with extensive occlusive dressings may suppress adrenocortical function.

Continuous application without interruption will result in local atrophy of the skin, striae, and superficial vascular dilatation, particularly on the face.

Prolonged use in the management of acne vulgaris should be avoided.

Use in psoriasis may lead to generalisation, excessive systemic absorption and rebound relapse on cessation of use.

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)

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 interactions**

None known.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

There are no or limited amount of data from the use of hydrocortisone in pregnant women. Studies in animals have shown reproductive toxicity.

Hydrocortisyl is not recommended during pregnancy and in women of childbearing potential not using contraception.

##### Lactation

Hydrocortisone/metabolites are excreted in human milk and have been identified in breastfed newborns/infants of treated women. There is insufficient information on the effects of hydrocortisone in newborns/infants.

Hydrocortisyl should not be used during breast-feeding.

##### Fertility

No data available.

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

None.

#### **4.8 Undesirable effects**

##### Skin and subcutaneous disorders:

Striae may occur especially in intertriginous areas.

Frequency not known: Urticaria

##### Investigations

Not known: Weight increase secondary to adrenal suppression (long term use)

##### Endocrine disorders:

Frequency not known: Pheochromocytoma crisis

##### Eye disorders:

Frequency not known: Chorioretinopathy, blurred vision, (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 HPRC Pharmacovigilance. Website: [www.hpra.ie](http://www.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: Discard 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 Limited 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**

November 2021