

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisyl Skin Ointment 1%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains hydrocortisone 1% w/w

Excipients- Contains wool fat 10% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment

A yellowish white, translucent, homogeneous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of corticosteroid-sensitive superficial dermatoses.

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 the active substance(s) or to any of the excipients listed in section 6.1.

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. May cause local skin reactions (e.g. contact dermatitis).

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 known.

4.8 Undesirable effects

Striae may occur especially in intertriginous areas.

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

Wool fat
Liquid paraffin
White soft paraffin

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

Tube caps are made from opaque high density polyethylene.

Not all pack sizes may be marketed.

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

PA 540/46/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 25 November 2009

10 DATE OF REVISION OF THE TEXT

October 2012