IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0030/014/001
Case No: 2057643

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

Novartis Consumer Health UK Limited

Wimblehurst Road, **Horsham**, **West Sussex RH12 5AB**, **United Kingdom**

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

Eurax Hydrocortisone Cream Crotamiton 10.0 %w/w Hydrocortisone 0.25 %w/w

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 **08/02/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Eurax Hydrocortisone Cream
Crotamiton 10.0 %w/w
Hydrocortisone 0.25 %w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Crotamiton 10.0% w/w
Hydrocortisone 0.25% w/w

Excipients:

Stearyl alcohol	25.00	%w/w
Propylene glycol	20.00	%w/w
Propyl parahydroxybenzoate (E216)	0.015	%w/w
Methyl parahydroxybenzoate (E218)	0.025	%w/w
Perfume (containing benzyl benzoate)	<0.125	%w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A white to cream coloured cream giving a homogeneous smear, apart from trapped air bubbles; odour characteristic of perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In corticosteroid sensitive dermatoses including intertrigo and in insect bite reactions.

4.2 Posology and method of administration

Method of application:

A thin layer of Eurax Hydrocortisone Cream should be applied to the affected area 2-3 times a day. Occlusive dressings should not be used. Treatment should be limited to 10-14 days or up to 7 days if applied to the face.

Use in the Elderly

Clinical evidence would indicate that no special dosage regime is necessary.

Use in Children

Eurax Hydrocortisone should be used with caution in infants and for not more than 7 days. Eurax Hydrocortisone should not be applied for more than once a day to large areas of the body surface in young children.

Route of administration: Cutaneous use.

4.3 Contraindications

Bacterial, viral or fungal infections of the skin.

Hypersensitivity to any component of the formulation. Acute exudative dermatoses.

Application to ulcerated areas.

4.4 Special warnings and precautions for use

Eurax Hydrocortisone should be used with caution in infants and for not more than 7 days; long-term continuous topical therapy should be avoided since this can lead to adrenal suppression even without occlusion.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

It is not known whether the active substances of Eurax Hydrocortisone and/or their metabolites pass into the breast milk after topical administration. Use in lactating mothers should only be at the doctor’s discretion.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Occasionally at the site of application signs of irritation such as a burning sensation, itching, contact dermatitis/contact allergy may occur. Treatment should be discontinued if patients experience severe irritation or sensitisation.

4.9 Overdose

Eurax Hydrocortisone is for application to the skin only. If accidental ingestion of large quantities occurs, there is no specific antidote and general measures to eliminate the drug and reduce its absorption should be undertaken. Symptomatic treatment should be administered as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A combination of a corticosteroid with an antipruritic for topical use.

5.2 Pharmacokinetic properties

No pharmacokinetic data on Eurax Hydrocortisone Cream are available.

5.3 Preclinical safety data

No additional data given.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearyl alcohol
Propylene glycol
White soft paraffin
Polyoxyl 40 stearate
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Sulphuric acid
Perfume Givaudan no. 45 (containing benzyl benzoate)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

30 months.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Collapsible aluminium tube.
Pack size: 30g.

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

Novartis Consumer UK Limited
Trading as Novartis Consumer Health
Wimblehurst Road
Horsham
West Sussex
RH12 5AB
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 30/14/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 May 1988

Date of last renewal: 12 May 2008

10 DATE OF REVISION OF THE TEXT

January 2010