IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0030/018/001
Case No: 2061350

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

Novartis Consumer Health UK Ltd

Wimblehurst Road, **Horsham**, **West Sussex RH12 5AB**, **England**

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

Eurax HC Cream

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 **12/06/2009**.

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 Hc Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Crotamiton 10% w/w and Hydrocortisone 0.25% w/w.

Excipients: also includes stearyl alcohol 25% w/w; propylene glycol 20% w/w; methyl hydroxybenzoate (E218) 0.025% w/w and propyl hydroxybenzoate (E216) 0.015% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A white to cream coloured cream with an odour characteristic of the perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Irritant contact dermatitis, allergic contact dermatitis, insect bite reactions, mild to moderate eczema.

4.2 Posology and method of administration

For external application.

Adults and children over 10:
Apply sparingly over a small area twice a day for a maximum period of seven days.
Occlusive dressing should not be used.

Not recommended for children under 10 without medical advice.

4.3 Contraindications

Hypersensitivity to any component of the formulation. Bacterial, viral or fungal infections of the skin. Acute exudative dermatoses. Application to ulcerated areas. Use on eyes/face, anogenital region, broken or infected skin including cold sores, acne and athletes foot.

4.4 Special warnings and precautions for use

Product labelling to include the following:

Do not use in pregnancy or breast feeding without medical advice.

Do not use on the eyes or face, the ano-genital region, or on broken, infected or weeping skin, including cold sores, acne and athletes foot.

If the condition does not improve within 7 days, consult your doctor.

For external use only.

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 Hc cream 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.

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 Hc cream 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 taken. Symptomatic treatment should be administered as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The product combines the anti-pruritic action of crotamiton with the anti-inflammatory and anti-allergic properties of hydrocortisone.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearyl alcohol
Propylene glycol
White soft paraffin

Polyoxyl 40 stearate
Methyl hydroxybenzoate (E218)
Propyl hydroxybenzoate (E216)
Perfume givaudan
Sulphuric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

30 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Internally lacquered aluminium tubes, each containing 15 g of cream.

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 Health UK Ltd
Wimblehurst Road
Horsham
West Sussex
RH12 5AB
England

8 MARKETING AUTHORISATION NUMBER

PA 30/18/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th September 1997

Date of last renewal: 5th September 2007

10 DATE OF REVISION OF THE TEXT

May 2008