NAME OF THE MEDICINAL PRODUCT
Eurax® Hc Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Crotamiton 10.0% w/w
Hydrocortisone 0.25% w/w
For excipients, see Section 6.1

3. PHARMACEUTICAL FORM
Cream.
A white to cream coloured cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Relief of inflammation and pruritus associated with:
Irritant contact dermatitis
Allergic contact dermatitis
Insect bite reactions
Mild to moderate eczema

4.2 Posology and method of administration
Adults and children over 10
Apply sparingly over a small area twice a day for a maximum period of 1 week. Occlusive dressings should not be used. Do not use in children under 10 without medical advice.
Eurax Hc is indicated for external use only.
Method of administration: For cutaneous use.

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 the eyes/face, ano-genital region, broken or infected skin including cold sores, acne and athlete's foot.

4.4 Special warnings and precautions for use

The product label includes the following warnings and precautions:

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 athlete's foot.

If the condition does not improve consult your doctor.

Keep all medicines out of the reach of children.

Contains hydrocortisone.

FOR EXTERNAL USE ONLY

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

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 and/or their metabolite(s) pass into the breast milk after topical administration. Use in lactating mothers should only be at the doctor's discretion.

Product label warning:

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

4.7 Effects on ability to drive and use machines

None stated.
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 undertaken. Symptomatic treatment should be administered as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Eurax Hc combines the antipruritic action of crotamiton with the anti-inflammatory and anti-allergic properties of hydrocortisone.

5.2 Pharmacokinetic properties
No pharmacokinetic data on Eurax Hc Cream are available.

5.3 Preclinical safety data
None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Stearyl alcohol
White soft paraffin
Polyoxyl 40 stearate
Propyl hydroxybenzoate
Propylene glycol
Methyl hydroxybenzoate
Perfume Givaudan No. 45

Sulphuric acid

Purified water

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6.2 Incompatibilities

None stated.

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6.3 Shelf life

30 months.

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6.4 Special precautions for storage

Do not store above 25°C.

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6.5 Nature and contents of container

Collapsible aluminium tube.

Pack size: 15g