SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Eurax Hydrocortisone Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredients:  Crotamiton 10.0% w/w
                    Hydrocortisone 0.25% w/w

3 PHARMACEUTICAL FORM
Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Eczema and dermatitis of all types including atopic eczema, photodermatitis, otitis externa, primary irritant and allergic dermatitis, intertrigo, prurigo nodularis, seborrhoeic dermatitis and insect bite reactions.

Route of Administration: Cutaneous use.

4.2 Posology and method of administration

Adults
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.

Paediatric population:
Eurax Hydrocortisone Cream should be used with caution in infants, particularly when used in the nappy region, and for not more than 7 days unless under medical supervision. Eurax Hydrocortisone Cream should not be applied more than once a day to large areas of the body surface in young children. See section 4.4 Special warnings and precautions for use.

Method of administration: For cutaneous use.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients (see section 6.1, List of excipients). Bacterial, viral or fungal infections of the skin. Acute exudative dermatoses. Application to ulcerated areas.

4.4 Special warnings and precautions for use
Eurax Hydrocortisone Cream is for external use only.
Caution should be used when applying the cream to infants and for not more than 7 days without medical supervision.
Long-term continuous topical therapy should be avoided since this can lead to adrenal suppression even without occlusion.
Occlusive dressings should not be used.
Avoid using a nappy if Eurax Hydrocortisone Cream is applied in the nappy region and restrict to one application per day if applied to a large area.
Eurax Hydrocortisone Cream should not be used in buccal mucosa or other mucous membranes and in or around the eyes since contact with the eyelids may give rise to conjunctival inflammation. In case of accidental contact with the eyes, or mucosa rinse thoroughly with running water.
Eurax Hydrocortisone Cream should not be applied in the presence of exudative wounds, broken skin, or very inflamed skin.
Eurax Hydrocortisone Cream contains propylene glycol which may cause skin irritation, stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis); propyl hydroxybenzoate and methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).
Eurax Hydrocortisone Cream should only be used during pregnancy or breast-feeding under medical supervision.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.
4.6 Fertility, Pregnancy and lactation

Pregnancy
There are no controlled studies of Eurax Hydrocortisone Cream in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. Therefore Eurax Hydrocortisone Cream is not recommended during pregnancy, especially in the first three months.

Breastfeeding
It is not known whether the active substances of Eurax Hydrocortisone Cream and/or their metabolite(s) pass into the breast milk after topical administration. Therefore mothers should not use Eurax Hydrocortisone Cream whilst breastfeeding unless under medical supervision.

4.7 Effects on ability to drive and use machines

Eurax Hydrocortisone Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed below by frequency. Frequencies are defined as: uncommon (>1/1,000 to < 1/100), rare (> 1/10,000 to < 1/1,000) and very rare (<1/10,000).

Skin and subcutaneous tissue disorders:

Uncommon: pruritus

Rare: contact dermatitis, hypersensitivity (including/rash, eczema, erythema, skin irritation, angioedema)

Treatment should be discontinued if severe irritation occurs.

In case of longer lasting administration skin atrophy, telangiectasia, striae, steroid induced acne, peroral dermatitis and hypertrichosis cannot be excluded.

4.9 Overdose

Symptoms

In cases of accidental ingestion, acute intoxication symptoms may be observed such as nausea, vomiting and irritation of the buccal, oesophageal and gastric mucosa. Rare cases of loss of consciousness and seizure were reported. General measures to eliminate the drug and reduce its absorption should be undertaken.

Although very rare, risk of methaemoglobinaemia exists in case of accidental ingestion as well as in case of excessive cutaneous absorption.

Management
The symptoms usually disappear following the discontinuation of the drug, but in severe cases treatment with methylene blue may be considered.

5  PHARMACOLOGICAL PROPERTIES

5.1  Pharmacodynamic properties
Pharmacotherapeutic group: other antipruritics (ATC code D04AX).

Eurax Hydrocortisone Cream combines the antipruritic action of crotamiton with the anti-inflammatory and anti-allergic properties of hydrocortisone.

Crotamiton is effective against various forms of pruritus. The relief it affords sets in rapidly and lasts about 6 to 10 hours. By relieving the itching, Eurax Hydrocortisone Cream prevents irritation of the skin caused by scratching and thus reduces the risk of secondary infection.

Hydrocortisone is a mild glucocorticoid with an anti-inflammatory, anti-allergic, and vasoconstrictive effect.

In inflammatory skin diseases of widely varying type and origin, it affords prompt relief and eliminates symptoms such as pruritus.

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

5.3  Preclinical safety data
No preclinical studies were performed using Eurax Hydrocortisone Cream. Preclinical data do not show teratogenic nor genotoxic risk for crotamiton.

Abnormalities of foetal development were observed following administration of corticosteroids to pregnant animals. Eurax Cream, a crotamiton containing cream, administered topically once daily for 3 months to rabbits was tolerated at doses of up to 200 mg/kg without signs of toxicity, apart from transient skin irritation. No sensitising or photo-sensitising potential has been observed in animal studies.

6  PHARMACEUTICAL PARTICULARS

6.1  List of excipients
Stearyl alcohol
White soft paraffin
Polyoxy 40 stearate
Propyl hydroxybenzoate
Propylene glycol
Methyl hydroxybenzoate
Perfume Givaudan no 45
Sulphuric acid
Purified water

6.2 Incompatibilities
None known.

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
Collapsible aluminium tube.
Pack Size: 30g.

6.6 Special precautions for disposal
Medicines should be kept out of the reach and sight of children.

7 MARKETING AUTHORISATION HOLDER
GlaxoSmithKline Consumer Healthcare (UK) Trading Limited,
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Brentford
Middlesex
TW8 9GS
United Kingdom

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