

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Eurax Hc Cream.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients: Crotamiton 10.0% w/w
 Hydrocortisone 0.25% w/w

Excipients with known effect

Stearyl alcohol 25% w/w
Propyl parahydroxybenzoate (E216) 0.015% w/w
Propylene glycol (E1520) 20% w/w
Methyl parahydroxybenzoate (E218) 0.025% w/w
Perfume 0.124 w/w (contains geraniol, citronellol, coumarin, benzyl alcohol, benzyl benzoate, citral, d-limonene, eugenol, linalool)

For the full list of 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

Apply sparingly over a small area twice a day for a maximum period of 1 week. Occlusive dressings should not be used.

Paediatric population:

Eurax Hc Cream can be used in children over 10 years of age and applied as described for adults.

Do not use in children under 10 years of age except under medical supervision.

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 Hc is indicated for external use only.

Do not use in children under 10 years of age except under medical supervision.

Occlusive dressings should not be used

Eurax Hc should not be used in buccal mucosa or other mucous membranes or 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 Hc should not be applied in the presence of exudative wounds, broken skin, or very inflamed skin.

Eurax Hc Cream contains propylene glycol which may cause skin irritation, stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis); propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce

product build up but not totally remove it.

This medicine contains 200 mg propylene glycol(E1520) in each gram of cream.

This medicine contains fragrance with benzyl alcohol, benzyl benzoate, citral, citronellol, coumarin, d-limonene, eugenol, geraniol and linalool which may cause allergic reactions.

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

The label will state mild steroid.

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 Hc Cream in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. Therefore Eurax Hc Cream is not recommended during pregnancy, especially in the first three months.

Breastfeeding

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

4.7 Effects on ability to drive and use machines

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

4 CLINICAL PARTICULARS

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/like 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.

Eye Disorders:

Not Known: Blurred Vision (see section 4.4)

Skin and Subcutaneous Tissue Disorders

Not known (cannot be estimated from available data) Withdrawal reactions - redness

of the skin which may extend to areas beyond the initial affected area, burning or

stinging sensation, itch, skin peeling, oozing pustules (see section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal

product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

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.

9.1 Pharmacodynamic properties

Pharmacotherapeutic group: other antipruritics (ATC code D07XA).

Eurax Hc 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 Hc 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.

Eurax Hc Cream is classed as a mild corticosteroid.

5.2 Pharmacokinetic properties

No pharmacokinetic data on Eurax Hc Cream are available.

5.3 Preclinical safety data

No preclinical studies were performed using Eurax Hc 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.

6.1 List of excipients

Stearyl alcohol

White soft paraffin

Polyoxyl 40 stearate

Propyl paraparahydroxybenzoate (E216)

Propylene glycol (E1520)

Methyl paraparahydroxybenzoate (E218)

Perfume Givaudan No. 45 (contains geraniol, citronellol, coumarin, benzyl alcohol, benzyl benzoate, citral, d-limonene, eugenol, linalool)

Sulphuric acid

Purified water

6.2 Incompatibilities

None stated.

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: 15g

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.

Linthwaite,

Huddersfield,

HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0460

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st September 1997

10 DATE OF REVISION OF THE TEXT

17/10/2024