# 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

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

## 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 parahydroxybenzoate(E216) and methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).
This medicine contains 200mg 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.

Eurax Hydrocortisone Cream should only be used during pregnancy or breast- feeding under medical supervision

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

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 advise 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 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 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 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.

Eurax Hydrocortisone Cream is classed as a mild corticosteroid.

## 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.

## 6.1 List of excipients

Stearyl alcohol
White soft paraffin
Polyoxy 40 stearate
Propyl parahydroxybenzoate (E216)
Propylene glycol (E1520)
Methyl parahydroxybenzoate (E218)
Perfume (contains contains geraniol, citronellol, coumarin, benzyl alcohol, benzyl benzoate, (citral, d-limonene, eugenol, linalool)

## 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

Thornton & Ross Ltd.
Linthwaite,
Huddersfield,
HD7 5QH, UK

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0459

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Original grant date: 17 January 1991
Date of renewal: 17 January 1996

## 10 DATE OF REVISION OF THE TEXT

17/10/2024