

## **1 NAME OF THE MEDICINAL PRODUCT**

Eurax Cream

Eurax Itch Relief Cream

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active ingredient: Crotamiton 10%.

Excipient(s) with known effects

Stearyl alcohol

Methyl Hydroxybenzoate

Sodium lauryl sulphate (0.45% w/w)

Perfume (contains geraniol, citronellol, coumarin, benzyl alcohol (0.0187%), benzyl benzoate (0.0047%), 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, with a slight characteristic odour.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

For the relief of itching and skin irritation caused by, for example, sunburn, dry eczema, itchy dermatitis, allergic rashes, hives, nettle rash, chickenpox, insect bites and stings, heat rashes and personal itching.

The treatment of scabies.

## **4 CLINICAL PARTICULARS**

### **4.2 Posology and method of administration**

### Pruritus

#### Adults (including the elderly):

Apply to the affected area 2-3 times daily. Eurax/ Eurax Itch Relief Cream will provide relief from irritation for 6 to 10 hours after each application. There are no special dosage recommendations in the elderly.

#### Paediatric population:

Eurax/ Eurax Itch Relief Cream can be used in children. However, for children under three years of age, usage should only be used under medical supervision and it should not be applied more than once a day.

### Scabies

#### Adults (including the elderly):

After the patient has taken a warm bath, the skin should be well dried and Eurax/ Eurax Itch Relief Cream rubbed into the entire body surface (excluding the face and scalp) until no traces of the preparation remain visible on the surface. The application should be repeated once daily, preferably in the evening, for a total of 3-5 days. Depending on the response, special attention should be paid to sites that are particularly susceptible to infestation by the mites (eg interdigital spaces, wrists, axillae and genitalia). Areas where there is pus formation should be covered with a dressing impregnated with Eurax/ Eurax Itch Relief Cream. While the treatment is in progress the patient may take a bath shortly before the next application. After completion of the treatment, a cleansing bath should be taken followed by a change of bed linen and underclothing.

There are no special dosage recommendations in the elderly.

#### Paediatric population:

Eurax/Eurax Itch Relief Cream can be used in children. For children under three years of age consult a doctor before use and do not apply more than once a day.

Method of administration: For cutaneous use.

## **4.3 Contraindications**

Acute exudative dermatoses. Hypersensitivity to the active substance or to any of the excipients (see section 6.1, List of excipients).

## **4 CLINICAL PARTICULARS**

### **4.4 Special warnings and precautions for use**

For external use only.

Eurax/Eurax Itch Relief Cream can be used for children; However, for children under three years of age usage should only be under medical supervision.

Should not be used in buccal mucosa 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 buccal mucosa rinse thoroughly with running water.

Should not be applied in the presence of exudative wounds, acute eczema, broken skin, or very inflamed skin. In the presence of eczematous scabies, eczema should be treated before the scabies.

Eurax/Eurax Itch Relief Cream contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

Eurax/Eurax Itch Relief Cream should only be used in pregnancy, breast feeding or for genital itching under medical supervision.

This medicine contains 0.45% w/w sodium lauryl sulphate in each application. Sodium lauryl sulphate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

This medicine contains fragrance with benzyl alcohol (0.0187%), benzyl benzoate(0.0047%), citral, citronellol, coumarin, d-limonene, eugenol, geraniol and linalool which may cause allergic reactions.

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.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

## **4 CLINICAL PARTICULARS**

### **4.6 Fertility, Pregnancy and lactation**

#### **Pregnancy**

There are no controlled studies of Eurax/ Eurax Itch Relief Cream in human pregnancy. Therefore Eurax/Eurax Itch Relief Cream is not recommended during pregnancy, especially in the first three months.

#### **Breastfeeding**

It is not known whether the active substance of Eurax/Eurax Itch Relief Cream passes into breast milk after topical administration. Therefore, mothers should not use Eurax/ Eurax Itch Relief Cream whilst breastfeeding unless directed by a physician. If Eurax/ Eurax Itch Relief Cream is used during breastfeeding it should not be applied to the nipple area.

Fertility

No data is available on the potential effects of crotamiton on fertility.

## 4 CLINICAL PARTICULARS

### 4.7 Effects on ability to drive and use machines

Eurax/Eurax Itch Relief Cream has no influence on the ability to drive and use machines.

### 4.8 Undesirable effects

#### Summary of the safety profile

The most commonly reported adverse reaction during treatment is pruritus. Contact dermatitis and hypersensitivity reactions like rash, eczema, erythema, skin irritation and angioedema may occur rarely.

#### Tabulated list of adverse reactions

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: *very common* ( $\geq 1/10$ ); *common* ( $\geq 1/100$  to  $< 1/10$ ); *uncommon* ( $\geq 1/1,000$  to  $< 1/100$ ); *rare* ( $\geq 1/10,000$  to  $< 1/1,000$ ); *very rare* ( $< 1/10,000$ ), or *not known* (can not to be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Class (SOC)	Adverse Reaction
<b>Frequency</b>	
<u>Skin and subcutaneous tissue disorders</u>	
Uncommon	Pruritus
Rare:	Contact dermatitis, hypersensitivity (like rash, eczema, erythema, skin irritation, angioedema)

Treatment should be discontinued if severe irritation occurs.

#### 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](http://www.mhra.gov.uk/yellowcard).

## **4.9 Overdose**

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.

Symptomatic treatment should be administered as appropriate. Moreover although very rare, risk of methaemoglobinaemia exists in case of accidental ingestion as well as in case of excessive cutaneous absorption. 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) and other ectoparasiticides, including scabicides (ATC code P03AX).

Crotamiton has a symptomatic action on pruritus and is an acaricide. As an acaricide agent, crotamiton is effective on the motor system of the mites by inducing irreversible cessation of spontaneous movements.

Eurax/Eurax Itch Relief Cream will provide relief from irritation for 6 to 10 hours after each application.

### **5.2 Pharmacokinetic properties**

Eurax penetrates rapidly into human skin. Low but measurable concentrations of crotamiton are found in plasma, with a maximum level after 4-10 hours, declining rapidly thereafter.

### **5.3 Preclinical safety data**

No preclinical studies were performed using Eurax 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 PROPERTIES**

### **6.1 List of excipients**

Methyl hydroxybenzoate  
Phenylethyl alcohol  
Glycerol  
Triethanolamine  
Sodium lauryl sulphate (0.45% w/w)  
Ethylene glycol monostearate  
Stearyl alcohol  
Strong ammonia solution 25%  
Stearic acid  
Hard paraffin  
White beeswax  
Perfume (contains geraniol, citronellol, coumarin, benzyl alcohol (0.0187%), benzyl benzoate (0.0047%), citral, d-limonene, eugenol, linalool).  
Purified water.

### **6.2 Incompatibilities**

None.

### **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 tube with an inner coating made of epoxy-phenol resin lacquer closed with a polyethylene screw cap, in a cardboard carton.

Pack sizes: 20, 30 and 100g

## **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 00240/0461

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

01/09/1997

## **10 DATE OF REVISION OF THE TEXT**

03/09/2021

