Name of the medicinal product

Eurax

1. Qualitative and quantitative composition

Active ingredient: crotamiton 10%.

For excipients see section 6.1.

2. Pharmaceutical form

Cream

Homogenous cream, practically white, with a faint characteristic odour.

3. Clinical particulars

3.1 Therapeutic indications

For the relief of pruritus and treatment of scabies.

3.2 Posology and method of administration

Pruritus

Adults:

Apply to the affected area 2-3 times daily. Eurax will provide relief from irritation for 6 to10 hours after each application. The same for severe cases that required longer treatment, since Eurax is well tolerated by the skin. Patients should be instructed to consult a doctor if there is no relief after 5 days of treatment.

Paediatric population:

Eurax can be used in children.

Children under three years of age: it should not be applied more than once a day. Consult a doctor before use.

Scabies

Adults:

After the patient has taken a warm bath, the skin should be well dried and Eurax 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. 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.

Paediatric population:

Eurax can be used in children.

Children under three years of age: do not apply more than once a day. Consult a doctor before use.

Method of administration: For cutaneous use.

3.3 Contraindications

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

3.4 Special warnings and precautions for use

For external use only.

Eurax 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 contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and propylene glycol which may cause skin irritation.

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

3.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

3.6 Fertility, pregnancy and lactation

Pregnancy

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

Breastfeeding

It is not known whether the active substance of Eurax passes into breast milk after topical administration. Therefore, mothers should not use Eurax whilst breastfeeding unless directed by a physician. If Eurax 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.

3.7 Effects on ability to drive and use machines

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

3.8 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* (≥ 1/10); *common* (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); *rare* (≥ 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) **Frequency**	**Adverse Reaction**
Skin and subcutaneous tissue disorders	
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 https://sideeffects.health.gov.il

3.9 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.

4. Pharmacological properties

4.1 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 will provide relief from irritation for 6 to 10 hours after each application.

4.2 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.

4.3 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.

5. Pharmaceutical particulars

5.1 List of excipients

Purified water, glycerol monostearate, propylene glycol, liquid paraffin, cetostearyl alcohol, isopropyl myristate, polyoxyl 40 stearate.

5.2 Incompatibilities

None.

5.3 Shelf life

The expiry date of the product is printed on the packaging materials.

5.4 Special precautions for storage

Store below 30°C.

5.5 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 g

5.6 Special precautions for disposal and other handling

None.

6. Marketing authorisation holder

DEVRIES & CO. Ltd. 32

HaBarzel St., Tel Aviv

7. Manufacturer

STADA Arzneimittel

AG Stadastrasse 2 –

18, 61118 Bad Vilbel,

Germany

8. Marketing authorisation number

127-17-22132

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