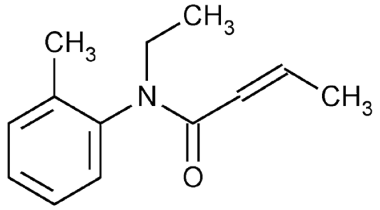
EURAX

Crotamiton BP

Name of the medicine

Active ingredient: Crotamiton 100 mg/g



Chemical structure:

Molecular formula: $C_{13}H_{17}NO$

CAS Registry Number: 483-63-6

Description

Eurax contains N-crotonyl-N-ethyl-o-toluidine (crotamiton).

Eurax Cream contains 100 mg/g (10%) crotamiton with the excipients: cetosteryl alcohol, glyceryl monostearate, isopropyl myristate, paraffin – liquid, PEG-40 stearate, propylene glycol, water - purified. Eurax Cream is a practically white, homogeneous cream, with a slight characteristic odour.

Eurax Lotion contains 100 mg/g (10%) crotamiton with the excipients:cetomacrogol 1000, citric acid monohydrate, glyceryl monostearate, octyldodecanol, perfume, phenethyl alcohol, propylene glycol, sorbic acid, water – purified, wax – emulsifying, wool fat. Eurax Lotion is a viscous, white to yellowish-white emulsion, with an odour of perfume.

Pharmacology

Pharmacotherapeutic group: other antipruritics (ATC code D04AX) and other ectoparasiticides, including scabicides (ATC code P03AX).

EURAX is effective against pruritus of various causes. Topical application has been shown to relieve the sensation of itching for periods up to 6 to 10 hours. This antipruritic activity is complemented by an antiseptic effect which prevents secondary infection.

In addition, EURAX is a specific acaricide and is therefore suitable for the treatment of scabies. EURAX is non-greasy and readily penetrates the skin. The lotion is preferable for application to hairy surfaces.

Indications

- Treatment of pruritus/itching due to nettlerash (hives), insect bites, and stings, sunburn, allergies, miliaria (prickly heat) senile, anal and genital pruritus.
- Treatment of scabies.
- Itching due to infestations with head lice (pediculosis capitis) body or pubic lice (Eurax Lotion).

Contraindications

- Hypersensitivity to the active ingredient or any other ingredients.
- In pregnancy, especially in the first trimester.

Precautions

- For external use only.
- Do not use in buccal mucosa and in or around the eyes. 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.
- Do not apply to exudative wounds, acute eczema, broken skin or very inflamed skin. In the presence of eczematous scabies, eczema should be treated before the scabies.
- Do not apply to a large area in small children.
- EURAX cream contains propylene glycol which may cause skin irritation and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- EURAX lotion contains propylene glycol which may cause skin irritation and sorbic acid, cetostearyl alcohol and wool fatwhich may cause local skin reactions (e.g. contact dermatitis).

Use in pregnancy (Category B2)

There are no controlled studies of EURAX in human pregnancy. Therefore, EURAX is not recommended during pregnancy, especially in the first 3 months.

Category B2:

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

Use in lactation

It is not known whether the active substance of EURAX passes into the breast milk after topical administration. Therefore mothers should not use EURAX while breastfeeding unless directed by a doctor. Nursing mothers should avoid applying EURAX in the area of the nipples.

Effects on fertility

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

Effects on ability to drive and use machines

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

Interactions

No interaction studies have been performed.

Adverse effects

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 (cannot be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

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.

Dosage and administration

Eurax is for external use only.

To treat itch (anti-pruritic agent)

EURAX should be rubbed gently into the affected areas 2 to 3 times daily. Patients using Eurax as self-medication should consult a doctor if the itching still persists after 5 days' treatment with Eurax.

To treat scabies (acaricide agent)

EURAX should be rubbed thinly and evenly over the entire body surface (except the face and scalp). Particular care should be taken to work the cream or lotion into skin folds e.g. between the fingers and toes, on the wrists and in the armpits and genital areas (avoiding contact with mucous membranes).The application should be repeated once daily, preferably in the evening, for 3 to 5 days depending on the response.

Patients may bath or shower while treatment is in progress but should reapply EURAX immediately after bathing and drying, and no more than once a day.

Bed linen and underclothing should be changed and thoroughly washed after the second application and on completion of the treatment.

EURAX should never be applied to the entire body surface of small children *(See Precautions).*

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.

Although very rare, risk of methaemoglobinaemia exists in case of accidental ingestion as well as in case of excessive cutaneous absorption. One case of percutaneous overdosage of crotamiton (Eurax cream) and suspicion of methaemoglobinaemia has been reported following extensive use in a 2½ month-old child.

In case of overdose, suspected overdose or accidental swallowing, please contact the Poisons Information Centre; phone: 13 11 26.

Presentation and storage conditions

Eurax Cream is available in aluminum tubes with an inner coating made of epoxy-phenol resin lacquer closed with polyethylene screw caps. It is available in tube size of 20 g.

Eurax Lotion is available in amber glass bottles, fitted with a low density polyethylene insert and white polypropylene guarantee caps. It is available in bottle size of 50 mL.

Store below 30^0C. Protect from heat.

Name and address of the sponsor

GlaxoSmithKline Consumer Healthcare

82 Hughes Ave Ermington NSW 2115 Australia

FREECALL Australia: 1800 028 533

®= Registered Trade Mark

Poison Schedule of the Medicine

Unscheduled

Date of first inclusion of Australian Register of Therapeutic Goods (the ARTG)

30 January 1987

Date of most recent amendment

Date of most recent amendment: 08 August 2016