

#### Composition

Active substance: Crotamiton. Cream: Crotamitonum 100 mg, Propylenglycolum, Excipient ad unguentum pro 1 g. Lotion: Crotamitonum 100 mg/ml, Propylenglycolum, Conserv.: 2-phenylaethanol., Acid. sorbic. (E 200), Aromatica, Adeps Ianae, Excip. ad emuls. pro 1 g.

# **Properties/Effects**

Eurax has acaricidic properties and exerts bacteriostatic activity on streptococci and staphylococci and soothes itching. Eurax penetrates easily into the skin without leaving any greasy or shiny deposits. The lotion is preferable for application to hairy and exposed parts of the body and for use on weeping skin.

# **Pharmacokinetics**

30 minutes following local application of Eurax, crotamiton can be detected not only on the skin surface and in deeper layers but also in the plasma. The plasma concentration is stable for approximately 24 hours and after several days' application, no plasma accumulation can be detected. Crotamiton is released into the blood flow evenly from the skin, which operates as a store, and is then eliminated rapidly.

# Indications/Method of use

For treatment of scabies and for relief of associated symptoms (pyoderma, pruritus).

# Dosage/Directions for use

After a hot bath, dry the skin thoroughly and apply Eurax by rubbing it lightly into the whole body surface (excluding the face and scalp) until no traces of the preparation remain visible on the surface. The application should be repeated preferably once a day in the evening for a total of 3 to 5 days depending on the response and paying special attention to sites that are particularly susceptible to infestation by the mites (interdigital spaces, wrists, axillae and genital areas). 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 each application. After completion of the treatment, a cleansing bath should be taken, followed by a change of bed-linen and underclothing. In small children, Eurax should never be applied more than once a day.

## **Restrictions on use**

*Contraindications:* Hypersensitivity to the active substance or to catalysts, e.g. lanolin in Eurax lotion.

Precautions: Eurax should not be allowed to come into contact with the conjunctiva. Where such contact occurs by accident, the eyes should be bathed with water. Treatment with the cream is not indicated in acutely inflamed, weeping skin conditions or skin wounds owing to the danger of systemic absorption.

Pregnancy, breast feeding: There are no available controlled studies in women or animals. In these circumstances, the preparation should only be applied if the potential benefit justifies the potential risk to the foetus. This applies

particularly to application during the first trimester. It is not known whether the active substance of Eurax passes into the breast milk. Nursing mothers should at all events avoid applying Eurax in the area of the nipples.

# **Undesirable side effects**

Eurax is generally well tolerated. Only in exceptional cases is irritation of the skin or contact allergy liable to occur; in such instances the preparation should be withdrawn.

# Interactions

No interaction has been found so far.

# **Overdosage**

A case of local overdosage of crotamiton with suspected methaemoglobinaemia was reported in a child of 2½ months following extensive use of Eurax cream.

# **Further remarks**

Storage: Eurax cream and lotion should not be used after the date indicated by  $\langle EXP \rangle$  on the pack. Cream and lotion: protect from heat (store below 30 °C). Medicines should be kept out of the reach of children.

#### Packaging

Cream: 20 and 60 g. Lotion: 50 ml.

#### **Novartis Consumer Health SA Nyon Switzerland**

Information updated: February 1996.

# (THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not buy yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

#### Keep medicament out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists

