

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Eurax

Cream

Composition:

The active ingredient and its concentration:

Crotamiton 10% w/w.

Inactive ingredients and allergens: See section 2, under 'Important information about some of this medicine's ingredients' and section 6, 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult with your doctor or pharmacist.

Use this medicine according to the instructions in the section about dosage in this leaflet. Consult with your pharmacist if you need further information. Consult with your doctor if the symptoms of illness get worse or do not improve after 5 days.

1. What is this medicine intended for?

The medicine is intended for the relief of itching and for the treatment of scabies.

Therapeutic group: scabicide, antipruritics.

2. Before using this medicine

Do not use this medicine:

- if you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (as specified in section 6).
- in instances of exudative dermatitis (weeping skin conditions).

Special warnings about using this medicine

Before using Eurax, tell your doctor:

- if you are suffering from genital itching.

Eurax should only be used for genital itching under medical supervision.

Do not apply Eurax near your mouth or eyes. In case of accidental contact, rinse your eyes or mouth with water.

Do not apply Eurax if you have acute eczema or very inflamed skin, or on open wounds or broken skin.

Children and adolescents

This medicine is also intended for children and adolescents. It is recommended to consult with your doctor before using this medicinal product on infants.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

Pregnancy

Eurax is not recommended for use during pregnancy, particularly during the first three months. Consult with your doctor before using Eurax.

Breastfeeding

If you are breastfeeding, consult with your doctor before using Eurax. It is not known whether Eurax passes into mother's milk. Therefore, do not use Eurax while breastfeeding, unless instructed to do so by your doctor. If Eurax is being used during breastfeeding, do not apply Eurax to the nipple area.

Driving and using machines

Eurax does not affect the ability to drive or use machines.

Important information about some of this medicine's ingredients

This medicinal product contains propylene glycol, which may cause a skin irritation.

This medicinal product contains cetostearyl alcohol which may cause a skin irritation (such as contact dermatitis).

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about dosage or about the mode of treatment with this medicinal product.

The recommended dosage is usually:

Pruritus (itching): Apply Eurax Cream to the affected skin 2-3 times a day until the itching is relieved. Eurax provides relief from itching for 6 to 10 hours after each application. Apply in this manner also for severe instances requiring prolonged treatment, because Eurax is well tolerated by the skin. If there is no relief from itching after 5 days of treatment, consult with your doctor.

Children under three years of age: Do not apply Eurax more than once a day. It is recommended to consult with your doctor before using this medicinal product on infants.

Scabies: The patient must first take a warm bath and thoroughly dry the skin. Then rub Eurax into the skin over the entire body (excluding the face and scalp) until no traces of the medicinal product remain visible on the skin. Repeat this procedure once a day, preferably in the evening, for 3-5 days. Depending on the response, pay special attention to areas that are particularly susceptible to infestation by mites (such as between the fingers and toes, wrists, armpits and genitalia). Cover skin surfaces exuding pus with a dressing impregnated with Eurax. During the period of treatment, the patient may take a bath shortly before the next application. After completing the treatment, take a cleansing bath and change bed linen and undergarments.

Children under three years of age: Consult with a doctor before using Eurax. Do not apply Eurax more than once a day.

Do not exceed the recommended dosage.

Do not swallow! This medicine is intended for external use only, for application to the skin. Avoid contact with eyes and mouth.

If you or a child have accidentally swallowed some of the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dosage every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult with your doctor or pharmacist.

4. Side effects

Like with all medicines, using Eurax may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop the treatment and see a doctor immediately

- if an allergic reaction appears, expressed as difficulties breathing or swallowing; swelling of the face, lips, tongue or throat; severe itching of the skin accompanied by a red rash or bumps. Rare.
- if a severe irritation develops.

Additional side effects

Uncommon side effects: pruritis (itching).

Rare side effects: rash, itchy rash, redness of the skin, eczema and swelling of the face and throat.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult with your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the tube and carton. The expiry date refers to the last day of that month.

Storage conditions

Store below 30°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

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

What the medicine looks like and contents of the pack:

Tube containing 20 grams of white cream with a typically mild odor.

Registration holder's name and address: Devries & Co. Ltd., 32 Habarzel St., Tel-Aviv, Israel.

Manufacturer's name and address: STADA Arzneimittel AG, Stadastrasse 2 – 18,
61118 Bad Vilbel, Germany.

Revised in June 2020.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
127-17-22132.