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

This medicine is dispensed without a doctor's prescription

Eurax

Cream

Active ingredient

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: antipruritics, parasiticides, including scabicides.

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).
- You suffer from weeping skin conditions (acute exudative dermatitis).

Special warnings about using this medicine

- Eurax Cream is intended for external use only. Do not use it around the eyes, or mouth. 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.
- Consult your doctor if you are suffering from genital itching.
- You may experience discomfort if you have sensitive skin.
- Stop using this cream if you experience irritation or other unwanted side effects.

Children and adolescents

This medicine is also intended for children and adolescents. However, consult with your doctor before use in children under 3 years of age.

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

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

Important information about some of this medicine's ingredients

This medicinal product contains propylene glycol, which may cause a skin irritation. 1 gram of cream contains 100 mg propylene glycol, equivalent to 10% w/w.

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: Consult with your doctor before use and do not apply Eurax more than once a day.

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 a doctor before use and 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.

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 <u>every time</u> 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.

If you experience any of these or other side effects, stop using the cream and seek medical advice:

- Severe skin irritation
- Difficulty breathing

Angioedema (swelling of the face, tongue or throat)

Additional side effects

Uncommon side effects:

• Pruritus (itching)

Rare side effects:

Contact dermatitis, hypersensitivity (such as rash, eczema, redness of the skin, skin irritation)

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.

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 February 2024.

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