

Eurax Hydrocortisone Cream – PL 00240/0459 - Leaflet

Eurax® Hydrocortisone Cream

Crotamiton 10.0% w/w and Hydrocortisone 0.25% w/w

Read all of this leaflet carefully because it contains important information for you.

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Eurax Hydrocortisone Cream is and what it is used for
2. Before you use Eurax Hydrocortisone Cream
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1. WHAT EURAX HYDROCORTISONE CREAM IS AND WHAT IT IS USED FOR

Eurax Hydrocortisone Cream is a skin cream to treat skin conditions such as eczema and dermatitis of all types, including those listed below, and also insect bite reactions:

- Intense itching due to atopic eczema and primary irritant and allergic dermatitis,
- UV light sensitivity (photodermatitis),
- inflammation of the outer ear (otitis externa),
- inflammation between skin folds (intertrigo),
- itching from hard skin nodules (prurigo nodularis),
- inflammation caused by excessive secretion of the skin glands (seborrhoeic dermatitis).

2. BEFORE YOU USE EURAX HYDROCORTISONE CREAM

Do not use Eurax Hydrocortisone Cream if you:

- are allergic (hypersensitive) to any of the ingredients of Eurax Hydrocortisone Cream (see Section 6 and Section 2 “Important information about some of the ingredients of Eurax Hydrocortisone Cream”),
- have a bacterial, viral or fungal infection of the skin
- have weeping open skin wounds (acute exudative dermatoses)
- have any ulcerated areas of skin
- are pregnant, or planning to become pregnant, or breast-feeding, without medical advice.

Do not put Eurax Hydrocortisone Cream in contact with the eyes (conjunctiva), mouth or mucous membranes. In case of contact with eyes, rinse immediately with water.

Take special care with Eurax Hydrocortisone Cream:

- use with caution in infants; especially in the nappy area; do not use for not more than 7 days
- long-term continuous use should be avoided as this can lead to adrenal problems.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a prescription.

There are no known interactions between Eurax Hydrocortisone Cream and other medicines.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines. Eurax Hydrocortisone Cream is not recommended for use in pregnancy as there is inadequate evidence of safety in pregnancy. Consult your doctor if you are breast-feeding because it is not known if the active substances of Eurax Hydrocortisone Cream pass into breast milk.

Driving and using machines

There is no evidence that Eurax Hydrocortisone Cream can affect your ability to drive or operate machinery.

Important information about some of the ingredients of Eurax Hydrocortisone Cream.

Eurax Hydrocortisone Cream contains.

stearyl alcohol, propyl hydroxybenzoate (E216), methyl hydroxybenzoate (E218) and fragrance with benzyl alcohol, benzyl benzoate, citral, citronellol, coumarin, d-limonene, eugenol, geraniol and linalool which may cause local allergic skin reactions. If this happens stop using the cream. This medicine contains 200mg propylene glycol (E1520) in each gram of cream which may cause skin irritation.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If your condition worsens during use consult a pharmacist or doctor – you may be experiencing an allergic reaction have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream/ointment without consulting a pharmacist or doctor. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation please seek medical advice before restarting treatment.

3. HOW TO USE EURAX HYDROCORTISONE CREAM

Adults and the Elderly

Apply a thin layer of Eurax Hydrocortisone Cream to the affected area 2-3 times a day. Do not cover the affected area with dressings. Do not use for more than 10-14 days (or for more than 7 days if applied to the face).

Children

Apply the cream once a day only in young children. A nappy should not be used if the cream is applied to the nappy area. Do not use the cream for more than 7 days in infants.

Eurax Hydrocortisone Cream should not be used for more than 7 days without seeking medical advice.

If you use more Eurax Hydrocortisone Cream than you should

Eurax Hydrocortisone is for application to the skin only.

If you or a child accidentally ingests large amounts of Eurax Hydrocortisone Cream, contact your doctor or hospital.

If you forget to use Eurax Hydrocortisone Cream

Do not apply more cream than you should to make up for a forgotten application.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Eurax Hydrocortisone Cream can cause side effects, although not everybody gets them.

Occasionally you may get skin irritation, such as a burning sensation, redness, itching, eczema, or contact dermatitis/contact allergy.

You should stop using the cream if you experience severe skin irritation, blurred vision (uncommon) or any visual disturbances.

If any of the side effects gets serious, or if you have any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Steroid withdrawal reaction:

If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

5. HOW TO STORE EURAX HYDROCORTISONE CREAM

Keep out of the sight and reach of children. Do not store above 25°C. Protect from heat.

Do not use Eurax Hydrocortisone Cream after the 'Use By' date which is stated on the carton. The 'Use By' date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Eurax Hydrocortisone Cream contains

The active ingredients are: Crotamiton 10.0% w/w and Hydrocortisone 0.25% w/w The other ingredients are: Stearyl alcohol, White soft paraffin, Polyoxy 40 stearate, Propyl hydroxybenzoate (E216), Propylene glycol, Methyl hydroxybenzoate (E218), Perfume (Contains: geraniol, citronellol, coumarin, benzyl alcohol, benzyl benzoate, citral, d-limonene, eugenol, linalool). Purified water

(see also Section 2 “Important information about some of the ingredients of Eurax Hydrocortisone Cream”).

What Eurax Hydrocortisone Cream looks like and contents of the pack

Eurax Hydrocortisone Cream is a white cream and is available in 30g aluminium tubes.

Marketing Authorisation Holder and Manufacturer

Thornton & Ross Ltd

Linthwaite,

Huddersfield,

HD7 5QH, UK

For any information about this medicinal product, please contact the Marketing Authorisation Holder.

This leaflet was last revised in October 2021