

ECOZONE® Cream

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about ECOZONE

ECOZONE cream is a topical preparation containing:

Econazole nitrate 1%

Dexamethasone 0.1% (as dexamethasone sodium phosphate)

Excipients are: vaseline, emulsifying wax, paraffin oil, methyl paraben, propyl paraben, and purified water.

Econazole nitrate is a broad spectrum imidazole antifungal active against dermatophytes and yeasts. A clinically relevant action against gram positive bacteria has also been found.

Dexamethasone is a topical corticosteroid sharing anti-inflammatory and anti-pruritic actions. It relieves inflammatory symptoms such as pruritus, erythema and edema.

ECOZONE is indicated for the topical treatment of dermatomycosis complicated by inflammatory and/or pruritic manifestations such as tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis.

ECOZONE cream is indicated for the treatment of inflammatory dermatoses superinfected by bacteria and/or fungi.

The way to use ECOZONE

Use as directed by your physician. Do not discontinue the treatment without consulting your doctor. ECOZONE cream is generally applied to the affected area as a thin film twice daily (morning and evening).

Duration of treatment

The duration of treatment ranges from 8 to 14 days depending on the severity of the condition and individual response to the first week of treatment.

This drug should not be used longer than 4 weeks.

In case of overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

If you suspect an overdose, irritation develops, or if the cream has been ingested, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Apply the missed dose as soon as you remember unless the next application is near. Go on applying the next scheduled dose as directed. Do not apply a double dose at once.

Contraindications

This drug should not be used in case of hypersensitivity to any of the components, to other corticosteroids or to imidazole derivatives.

Precautions

- This medication is for external use only. Avoid contact with the eyes or the mouth.
- Don't use this medication for any disorder other than for which it was prescribed or for longer than the prescribed time period.
- This medication is to be used for the full prescribed treatment time, even though the symptoms may have improved.
- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by your doctor.
- You should avoid sources of infection or reinfection.
- For athlete's foot, wear well-fitting and ventilated shoes and change shoes and socks at least once a day.
- Ask your doctor about the use of this medicine in case of pregnancy or lactation. Avoid the use of this drug during the first trimester of pregnancy.

-Notify your doctor if the condition being treated gets worse, or if burning, swelling or redness develops. Report any signs of local adverse reactions.

-Do not increase the dose without consulting your doctor. More frequent applications may increase the risk of side effects without ameliorating the therapeutic effects.

-Children may be more susceptible to topical corticosteroid-induced systemic toxicity than adults. Do not use for children without medical advice.

Association with other medications

Please inform your doctor if you are using any other medication. Do not put cosmetics or other skin products over the treated area unless directed by your physician. You should avoid preparations that may dry or irritate your skin. Other corticosteroid containing products should not be used with this cream without first talking to your doctor.

Adverse reactions

The short course of treatment with this medication limits the occurrence of adverse reactions.

The following local adverse reactions are reported infrequently with this drug and may occur more frequently with the use of occlusive dressings. They include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, secondary infection or skin atrophy.

The use over large surface areas, prolonged use and the addition of occlusive dressings increase systemic absorption of topical corticosteroids and the risk of systemic side effects.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

ECOZONE cream, econazole nitrate 1% and dexamethasone 0.1%, tube of 20 grams

Revision date: 07/2015

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