

FLUOCINOLONE ACETONIDE
0.025% 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 FLUOCINOLONE ACETONIDE

FLUOCINOLONE ACETONIDE cream is a topical preparation containing 0.025% fluocinolone acetonide.

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

FLUOCINOLONE ACETONIDE cream is indicated for the relief of the inflammatory and pruritic manifestations of acute or chronic corticosteroid-responsive dermatoses such as:

Contact dermatitis, atopic dermatitis, seborrheic dermatitis, localized neurodermatitis (lichen simplex chronicus), insect and arthropod bite reactions, first- and second-degree localized burns and sunburns, psoriasis, intertrigo, severe diaper rash, mycosis fungoides, anogenital pruritus, skin rash, the inflammatory phase of xerosis (abnormal dryness of the skin), discoid lupus erythematosus, and granuloma annulare.

FLUOCINOLONE ACETONIDE may be used with the addition of a suitable topical antibacterial or antifungal in the treatment of infected skin.

The way to use FLUOCINOLONE ACETONIDE

Wash and dry your hands before using. Clean and dry the affected area. Apply a thin film of medication to the affected area and gently rub in, usually 2-4 times daily depending on the severity of the condition or as directed by your doctor. Do not bandage, cover, or wrap the area unless directed to do so by your doctor.

If used in the diaper area on an infant, do not use tight-fitting diapers.

Duration of treatment

As with other corticosteroids, therapy should be discontinued when control is achieved. Contact your doctor if no improvement is seen within 2 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.

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.

Precautions

- This medication is for external use only. Avoid contact with the eyes. If contact occurs, rinse thoroughly with water.
- Don't use this medication for any disorder other than for which it was prescribed or for longer than the prescribed time period.
- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by your doctor.
- Ask your doctor about the use of this medicine in case of pregnancy or lactation. This cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Notify your doctor if the condition being treated gets worse. Report any signs of local adverse reactions.
- Do not increase number of applications without consulting your doctor. More frequent applications may increase the risk of side effects without ameliorating the therapeutic effects.

- In the presence of skin infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.
- 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 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, edema, rash, erythema, stinging, peeling, urticaria, skin fissures, 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.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°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

FLUOCINOLONE ACETONIDE 0.025% cream, tube of 15 grams

Revision date: 05/2008