Fluocinonide Cream USP, 0.1% (Insert-Front)

HIGHLIGHTS OF PRESCRIBING INFORMATION

FLUOCINONIDE CREAM USP 0.1% (TOPICAL) TO TREAT ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER WITH SKIN CONDITIONS THAT ARE CAUSED BY RED, FLAKY, AND ITCHY SKIN

DOSAGE FORMS AND STRENGTHS: Fluocinonide cream USP, 0.1% once or twice daily to the affected skin areas.

CONTRAINDICATIONS: Fluocinonide cream should not be used in the face, groin, axillae, or elsewhere on the skin if the patient has not been diagnosed by a physician as a candidate for the use of topical corticosteroid. In addition, the use of corticosteroids in the treatment of acne vulgaris, eczema, and other skin conditions, should be limited to those patients whose skin is considered to be relatively resistant, as determined by the physician. This may occur during treatment or upon withdrawal of treatment with corticosteroid.
Fluocinonide cream is a corticosteroid medication used to treat various skin conditions such as eczema, dermatitis, and keratosis pilaris. It works by reducing inflammation and swelling.

**Ingredients:**
- Active ingredient: Fluocinonide USP 0.1%
- Inactive ingredients: Propylene glycol, glyceryl stearate (and) PEG-100 stearate, glyceryl diethylene glycol monoethyl ether, glyceryl stearate, polyethylene glycol 200, polyethylene glycol 400, purified water, carbomer homopolymer, disopropylamine and anhydrous citric acid.

**How to use:**
- Apply a thin layer of cream to the affected skin area and cover it with a layer of occlusive dressing, if desired.
- Wash hands after using the cream.
- Avoid contact with the eyes or mouth.

**Side effects:**
- Common: Burning, dryness, itching, redness, pain, rash, stinging, swelling.
- Serious: Weight loss, muscle weakness, nausea, vomiting, diarrhea, numbness or tingling in the fingers or toes, speech problems.

**Dosage and Administration:**
- Apply the cream once or twice daily as directed by the physician.
- Do not apply to破损 area, infections, or wounds.
- Keep the tube tightly closed.

**Warnings and Precautions:**
- Do not use if you are allergic to any of the ingredients.
- Avoid use if you have tuberculosis or any other active viral or fungal infections.
- Do not use on areas that are broken or cut.
- Do not use for any other condition without consulting a doctor.

**Interactions:**
- Do not use with other topical medications unless directed by a physician.
- Use caution when combining with other medications that may reduce absorption or enhance systemic effects of fluocinonide.

**Precautions:**
- Systemic side effects may occur with prolonged use, especially on large areas of skin.
- Use cautiously in elderly, debilitated, or malnourished persons.

**Contraindications:**
- Avoid use on skin that has been compromised, has infections, or is irritated.
- Do not use if you have a history of skin reactions to corticosteroids.

**Side effects:**
- Skin thinning, increased skin fragility, and increased skin sensitivity.
- Changes in growth or development in children.
- Rebound effects, including increased inflammation or irritation after discontinuing treatment.

**Overdosage:**
- No specific treatment is required for an overdose.
- Avoid concomitant use with other medications that may affect skin absorption or systemic effects.

**Precautions for Pregnancy and Nursing:**
- Use only if the potential benefit justifies the potential risk to the fetus.
- Avoid using during pregnancy and breastfeeding unless the potential benefit justifies the potential risk to the fetus.

**Special Considerations:**
- Do not stop using fluocinonide cream without consulting a doctor.
- Avoid excessive use or use for longer than recommended.
- Discontinue use if irritation or sensitivity occurs.

**Patient Counseling Information:**
- Instruct patients to wash their hands after applying the cream.
- Advise patients to avoid contact with the eyes or mouth.
- Do not use fluocinonide cream for conditions other than those for which it was prescribed.

**Medication Guide:**
- A Medication Guide is available for fluocinonide cream.

**References:**
- National Library of Medicine, National Institutes of Health, 2021.

**Manufacturer:**
- Glenmark Pharmaceuticals Ltd.
- Glenmark Pharmaceuticals Inc., USA
- Glenmark Pharmaceuticals Ltd.
- Glenmark Pharmaceuticals Inc., USA

**Related Products:**
- Fluocinonide cream USP 0.1% (Glenmark)
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