**FULL PRESCRIBING INFORMATION**

**INDICATIONS AND USAGE**

Fluocinonide Cream USP, 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of various dermatoses characterized in most, but not all cases, by lesions such as those of nummular eczema, atopic dermatitis, discoid lupus erythematosus,接触性皮炎，银屑病(plaque-type psoriasis), dermatitis herpetiformis, and seborrheic dermatitis. It is also effective in the management of certain cutaneous manifestations of dermatitis caused by atop dermatitis or by contact dermatitis. Fluocinonide is an almost odorless white to creamy white crystalline powder. It is practically insoluble in water. 

**CONTRAINDICATIONS**

Fluocinonide Cream USP, 0.1% is contraindicated in the presence of skin infections caused by fungi or by bacteria.

**WARNING**

Because of the potential for systemic absorption, use of topical corticosteroids, including Fluocinonide Cream USP, 0.1%, should be limited to the area specified in the INDICATIONS AND USAGE section, and the duration should be the minimum necessary to control symptoms. 

**PRECAUTIONS**

**General**

Fluocinonide Cream USP, 0.1% is not intended for systemic administration. Topical corticosteroids are absorbed from the skin at varying rates and in varying amounts, with significant individual variation. Prognostic factors include the site and length of application, the amount and strength of the topical corticosteroid, and the integrity of the epidermis. If excessive local absorption occurs, systemic glucocorticoid effects may result. 

**Nervous System Disorders:**

Most of the systemic effects of topical corticosteroids, including Fluocinonide Cream USP, 0.1%, are observed in patients who abuse these drugs. 

**Immunologic Reactions:**

Systemic effects, including adrenocortical insufficiency, may also occur when topical corticosteroids, including Fluocinonide Cream USP, 0.1%, are administered. 

**Local Adverse Reactions**

Fluocinonide Cream USP, 0.1% is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of various dermatoses characterized in most, but not all cases, by lesions such as those of nummular eczema, atopic dermatitis, discoid lupus erythematosus,接触性皮炎，银屑病(plaque-type psoriasis), dermatitis herpetiformis, and seborrheic dermatitis. Fluocinonide is an almost odorless white to creamy white crystalline powder. It is practically insoluble in water. 

**ADVERSE REACTIONS**

**Topical Sites**

Occasionally, adverse effects may occur from the use of topical corticosteroids. Although the frequency of these reactions is low, they may be more likely to occur with occlusive use, prolonged use, or use of higher potency products. Staining of the skin has occurred with the use of fluocinonide cream. 

**Systemic Effects**

There are reports of patients developing Cushing syndrome after the use of topical corticosteroids, including Fluocinonide Cream USP, 0.1%. 

**OVERDOSAGE**

Systemic administration of topical corticosteroids has resulted inemblema cutis medicamentosa and the occurrence of hypoadrenalism after sudden withdrawal of high-potency topical steroids. 

**EVALUATION OF ADVERSE REACTIONS**

**Physical Examination**

Appropriate physical examination, laboratory evaluation and other diagnostic procedures, as indicated, should be performed to establish the presence or absence of a disease or condition that could be expected to respond to this drug. 

**TREATMENT OF OVERDOSAGE**

Topical corticosteroids are administered locally and are not subject to overdosage. 

**DERMATOLOGIC ADVERSE REACTIONS**

When occlusive dressings are used, the original application site may be increased and the total amount of topical corticosteroids applied daily to all body surface areas may increase. 

**IMMUNOLOGIC REACTIONS**

Systemic effects, including adrenocortical insufficiency, may also occur with the use of topical corticosteroids, including Fluocinonide Cream USP, 0.1%. 

**BURNING**

Burning may develop after use of more than one product at the same time, or after prolonged use of topical corticosteroids, including Fluocinonide Cream USP, 0.1%. 

**HYPERSensitivity**

At times, minor forms of hypersensitivity may develop, such as a localized nonscarring hypersensitivity. In such cases, the drug should be discontinued and the application site observed. 

**APPLICATION**

Fluocinonide Cream USP, 0.1% is a topical corticosteroid. Local corticosteroids are prescription-only antipruritic/emollient agents indicated for the relief of the inflammatory and pruritic manifestations of various dermatoses characterized in most, but not all cases, by lesions such as those of nummular eczema, atopic dermatitis, discoid lupus erythematosus,接触性皮炎，银屑病(plaque-type psoriasis), dermatitis herpetiformis, and seborrheic dermatitis. 

**PREGNANCY**

Studies conducted in pregnant women have not demonstrated any adverse effects associated with the use of Fluocinonide Cream USP, 0.1%. Fluocinonide is classified as Pregnancy Category C according to the USP classification system. 

**NURSING MOTHERS**

It is not known whether Fluocinonide Cream USP, 0.1% is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Fluocinonide Cream USP, 0.1% is administered to a nursing mother. 

**PARKINSON DISEASE**

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or www.perrigo.com.
PATIENT INFORMATION

Fluocinonide Cream USP, 0.1%

Important: For skin use only. Do not get Fluocinonide Cream USP, 0.1% in your eyes, mouth, or vagina. Not for use on the face, groin, or underarms.

Read the Patient Information that comes with Fluocinonide Cream USP, 0.1% before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your doctor about your condition or treatment.

What is Fluocinonide Cream USP, 0.1%?

Fluocinonide Cream USP, 0.1% is a prescription corticosteroid medicine used on the skin (topical) to treat adults and children 12 years and older with certain skin conditions that cause red, flaky, and itchy skin.

- You should not use Fluocinonide Cream USP, 0.1% for longer than 2 weeks in a row.
- You should not use more than 60 grams of Fluocinonide Cream USP, 0.1% or more than half of the 120 gram tube in 1 week.
- Fluocinonide Cream USP, 0.1% should not be used:
  - if you have skin swelling or redness on the nose or face (rosacea)
  - for a scaly or bumpy rash around your mouth (perioral dermatitis)
  - on your face, underarms, or groin area

It is not known if Fluocinonide Cream USP, 0.1% is safe and effective in children under 12 years of age.

What should I tell my doctor before using Fluocinonide Cream USP, 0.1%?

Before using Fluocinonide Cream USP, 0.1%, tell your doctor if you:
- have had irritation or other skin reaction to a steroid medicine in the past
- have adrenal gland problems
- plan to have surgery
- are pregnant or plan to become pregnant. It is not known if Fluocinonide Cream USP, 0.1% will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breastfeed. It is not known if Fluocinonide Cream USP, 0.1% passes into your breast milk. Talk to your doctor about the best way to feed your baby if you use Fluocinonide Cream USP, 0.1%

Tell your doctor about all the medicine you take including prescriptions and non-prescriptions medicines, vitamins, and herbal supplements.

- Especially tell your doctor if you take a corticosteroid medicine by mouth or use other products on your skin that contain corticosteroids.
- Ask your doctor or pharmacist if you are not sure.
- Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

How should I use Fluocinonide Cream USP, 0.1%?

- See “What is Fluocinonide Cream USP, 0.1%?”
- Use Fluocinonide Cream USP, 0.1% exactly as your doctor tells you.
- This medicine is for use on the skin only. Do not use Fluocinonide Cream USP, 0.1% in your eyes, mouth or vagina.
- Wash your hands after you use Fluocinonide Cream USP, 0.1%.
- Do not use Fluocinonide Cream USP, 0.1% for longer than 2 weeks in a row.
- Do not use Fluocinonide Cream USP, 0.1% before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your doctor about your condition or treatment.
- Do not bandage or cover the skin treated with Fluocinonide Cream USP, 0.1% unless your doctor tells you to.

What are the possible side effects with Fluocinonide Cream USP, 0.1%?

Fluocinonide Cream USP, 0.1% may cause side effects, including:
- Cushing’s syndrome, when the body is exposed to too much of the hormone cortisol.
  - Your doctor may do tests to check for this. Symptoms can include:
    - weight gain, especially around your upper back and midsection
    - slow healing of cuts, insect bites and infections
    - tiredness and muscle weakness
    - depression, anxiety and irritability
    - roundness of your face (moon face)
    - new or worsening high blood pressure

The most common side effect of Fluocinonide Cream USP, 0.1% is burning of your skin treated with Fluocinonide Cream USP, 0.1%.

- Talk to your doctor about any side effect that bothers you or that does not go away.
- These are not all the side effects with Fluocinonide Cream USP, 0.1%.
- See “What is Fluocinonide Cream USP, 0.1%?”

How should I store Fluocinonide Cream USP, 0.1%?

- Store Fluocinonide Cream USP, 0.1% at room temperature, between 20-25°C (68-77°F) [see USP Controlled Room Temperature].
- Keep the tube tightly closed.

Keep Fluocinonide Cream USP, 0.1% and all medicines out of the reach of children.

General information about Fluocinonide Cream USP, 0.1%

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use Fluocinonide Cream USP, 0.1% for a condition for which it was not prescribed. Do not give Fluocinonide Cream USP, 0.1% to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Fluocinonide Cream USP, 0.1%. If you would like more information, talk with your doctor. You can also ask your pharmacist or doctor for information about Fluocinonide Cream USP, 0.1% that is written for healthcare professionals.

What are the ingredients in Fluocinonide Cream USP, 0.1%?

Active ingredient: fluocinonide 0.1%

Inactive ingredients: carbopol 980, citric acid, disopropylamine, glycercin, glycercyl monostearate, glycercyl stearate, isostearic acid, PEG-100 stearate, polyethylene glycol monomethyl ether, propylene glycol, and water.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Rx Only

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