Fluocinonide Cream USP, 0.1%

**Section Title: Fluocinonide**

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Fluocinonide Cream USP, 0.1% contains fluocinonide, a synthetic corticosteroid for topical dermatologic use. Fluocinonide has the chemical name $6\alpha, 9$-difluoro-$11\beta, 16\alpha, 17, 21$-tetrahydroxypregna-$1, 4$-diene-$3, 20$-dione, cyclic $16, 17$-acetal with acetone, $21$-acetate. It may be represented by the following chemical structural formula and nomenclature.

![Chemical Structure of Fluocinonide](image)

Fluocinonide has a molecular formula of $C_{26}H_{32}F_{2}O_{7}$ and a molecular weight of 494.52. Fluocinonide is an almost odorless white to off-white crystalline powder. It is insoluble in water and slightly soluble in ethanol.

Each gram of Fluocinonide Cream USP, 0.1% contains 1mg of fluocinonide in an off-white cream base.

**Section Title: Indications and Usage**

Fluocinonide Cream USP, 0.1% is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 12 years of age or older.

Fluocinonide Cream USP, 0.1% is used to treat a variety of skin conditions (e.g., psoriasis, eczema, dermatitis, allergies, and rash). This medication reduces the swelling, itching, and redness that can occur in these skin conditions. It can also heal the rough, scaly patches on the skin seen with psoriasis.

For topical use only. This medication should only be used on the skin. Fluocinonide Cream USP, 0.1% is not for ophthalmic, oral, or intravaginal use. It should not be used in the treatment of rosacea or perioral dermatitis and should not be used on the face, groin, or axillae.
For Psoriasis - apply a thin layer of Fluocinonide Cream USP, 0.1% once or twice daily to the affected skin area as directed by a physician. For the Treatment of psoriasis, a twice daily application has been shown to be more effective in achieving treatment success during two weeks of treatment.

For Atopic Dermatitis - apply a thin layer of Fluocinonide Cream USP, 0.1% once daily to the affected skin area as directed by a physician. For the treatment of atopic dermatitis, once daily application has been shown to be as effective as twice daily use in achieving treatment success during two weeks of treatment.

For corticosteroid responsive dermatoses, other than psoriasis or atopic dermatitis - apply a thin layer of Fluocinonide Cream USP, 0.1% once or twice daily to the affected skin areas as directed by a physician.

Section Title: Dosage and Administration

Topical corticosteroids are applied to the affected area as a thin film, two to four times daily depending on the severity of the condition.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

Fluocinonide Cream USP, 0.1% use beyond two consecutive weeks is not recommended and total dosage should not exceed 60g per week, as the safety of Fluocinonide Cream USP, 0.1% for longer than two weeks has not been determined. Furthermore, the drug has the potential to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Fluocinonide Cream USP, 0.1% use should be discontinued when control of the disease is achieved.

Section Title: Warnings and Precautions

Systemic absorption of topical corticosteroids, including Fluocinonide Cream USP, 0.1%, can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression, Cushing’s syndrome, hyperglycemia, and manifestations of latent diabetes mellitus in some patients. The use of Fluocinonide Cream USP, 0.1% for longer than two weeks may suppress the immune system.

Because of the potential of systemic absorption associated with topical corticosteroids, including Fluocinonide Cream USP, 0.1%, patients may be required to be evaluated periodically for evidence of HPA axis suppression by using an ACTH stimulation test. Conditions that predispose a patient to HPA axis suppression include the application of more potent steroids, use over large surface areas, prolonged periods of use, addition of occlusive dressings, use on an altered skin barrier and use in patients with liver failure.

If HPA axis suppression is noted, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Upon withdrawal and discontinuation of the drug, recovery of HPA axis function is generally prompt and complete.
Infrequently, signs and symptoms of adrenal insufficiency may occur, requiring supplemental systemic corticosteroids.

Pediatric patients, due to their larger skin surface-to-body-mass ratios, may absorb proportionally larger amounts of topical corticosteroids than adults, and thus be more susceptible to systemic toxicity.

As with any topical corticosteroid product, use of more than one corticosteroid-containing product simultaneously may increase the total systemic absorption of topical corticosteroids.

**Pregnancy: Teratogenic Effects. Pregnancy Category C:**
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some of the more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids, including **Fluocinonide Cream USP, 0.1%** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

**Nursing Mothers**
Systemically administered corticosteroids appear in human milk and can suppress growth and interfere with endogenous corticosteroid production. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

**Pediatric Use**
Safety and efficacy of **Fluocinonide Cream USP, 0.1%** in pediatric patients younger than 12 years of age have not been established. Therefore, use in pediatric patients younger than 12 years of age is not recommended.

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing’s syndrome than mature patients due to their higher ratio of skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing’s syndrome, and intracranial hypertension have been documented in pediatric patients receiving topical corticosteroid treatments. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, postponed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Signs of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.
Chronic corticosteroid therapy may impede the growth and development of pediatric patients. Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen.

Geriatric Use
In clinical studies, there is insufficient data of subjects aged 65 and older to establish whether they respond differently from younger subjects.

Adverse Reactions
Local adverse reactions may occur more frequently with occlusive use, prolonged use or use of more potent corticosteroids. The following local adverse reactions may occur: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. Some local adverse reactions may be irreversible.

If an irritation presents, Fluocinonide Cream USP, 0.1% should be discontinued and appropriate therapy instituted. In the presence of a dermatological infection, an appropriate antifungal or antibacterial agent should be administered. Fluocinonide Cream USP, 0.1% should be discontinued until the infection has been adequately controlled.

Section Title: Clinical Pharmacology

Mechanism of Action
Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions and play a vital role in cellular signaling, immune function, inflammation, and protein regulation. However, the precise mechanism of action of Fluocinonide Cream USP, 0.1% in corticosteroid responsive dermatoses is undetermined. Several laboratory methodologies including vasoconstrictor assays, are utilized to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics
The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Presence of inflammation and other disease processes in the skin increase percutaneous absorption. Occlusive dressings significantly increase the percutaneous absorption of topical corticosteroids. Therefore, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses.

Once absorbed through the skin, Fluocinonide Cream USP, 0.1% is handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound in plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.
Section Title: How Supplied/Storage and Handling

Fluocinonide Cream USP, 0.1% is white to off-white in color and is supplied in tubes:

120g (NDC 45861-064-01)

Store at controlled room temperature: 20-25°C (68-77°F)

Keep the tube tightly closed.

Section Title: Patient Counseling Information

Rx Only

Manufactured By:

Dqquared Pharmaceuticals
4050 E. Cotton Center Blvd., Suite 63
Phoeniz, AZ 85040

Distributed By:

Pharmaceutica North America, Inc.