Safety Data Sheet
Fluocinonide Cream, USP
Strength: 0.1% **Pack Size:** 30 gm, 60 gm, 120 gm **NDC** 72578-087-06, 72578-087-02, 72578-087-07 **Revision No.:** 01

Emergency Overview

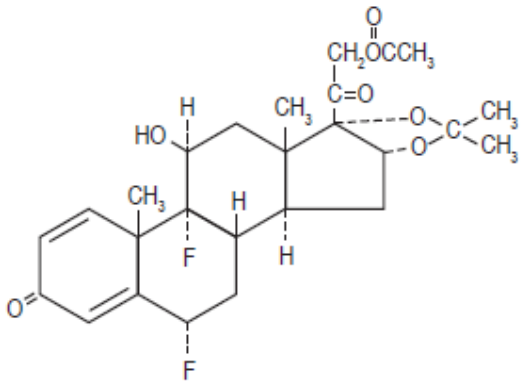
Fluocinonide cream USP, 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years of age or older.

Section 1 : Identification

Product Name: FLUOCINONIDE cream USP, 0.1% (for topical use)

Formula: $C_{26}H_{32}F_2O_7$

Chemical Name: 6 alpha, 9 alpha- difluoro-11 beta, 21-dihydroxy-16 alpha, 17 alpha- isopropylidenedioxypregna-1, 4-diene-3, 20-dione 21-acetate



Molecular Weight: 494.58 g/mol

Description: Fluocinonide cream USP, 0.1% contains fluocinonide, a synthetic corticosteroid for topical dermatologic use. The corticosteroids constitute a class of primarily synthetic steroids used topically as anti-inflammatory and antipruritic agents.

Dosage forms and strengths: Each gram of fluocinonide cream, USP contains 1 mg of fluocinonide, USP.
Fluocinonide cream USP, 0.1% is white to off white cream, free from lumps and foreign matter with no phase separation.

Manufacturer / supplier identification

Company Cadila Healthcare Ltd. Ahmedabad, India
Address Zydus Cadila, Topical Formulation facility. Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N. H 8A, Ahmedabad -382210 India.

Contact for information Tel.:+91 2717-616430 Fax: +91 2717-616430
Emergency Telephone No Tel.:+91 2717-616401

Recommended use / Therapeutic Category	For topical use only. Fluocinonide cream is not for ophthalmic, oral, or intravaginal use. **Psoriasis:** apply a thin layer once or twice daily to the affected skin areas. **Atopic Dermatitis:** apply a thin layer once daily to the affected skin areas. **Corticosteroid Responsive Dermatoses, other than psoriasis or atopic dermatitis:** apply a thin layer once or twice daily to the affected areas.
Restriction on Use / Contraindications	• Treatment beyond 2 consecutive weeks is not recommended and the total dosage should not exceed 60 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. • Avoid use on the face, groin, or axillae. • Avoid use in perioral dermatitis or rosacea.

Section 2 : Hazard (s) Identification

Dose and Administration	For topical use only. Fluocinonide cream is not for ophthalmic, oral, or intravaginal use. For psoriasis, apply a thin layer of fluocinonide cream once or twice daily to the affected skin areas as directed by a physician. Twice daily application for the treatment of psoriasis has been shown to be more effective in achieving treatment success during 2 weeks of treatment. For atopic dermatitis, apply a thin layer of fluocinonide cream once daily to the affected skin areas as directed by a physician. Once daily application for the treatment of atopic dermatitis has been shown to be as effective as twice daily treatment in achieving treatment success during 2 weeks of treatment. For corticosteroid responsive dermatoses, other than psoriasis or atopic dermatitis, apply a thin layer of fluocinonide cream once or twice daily to the affected areas as directed by a physician.
Adverse effects	Fatal if swallowed. Causes serious eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs (Endocrine system) through prolonged or repeated exposure. **Clinical Trials Experience** Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. In clinical trials, a total of 443 adult subjects with atopic dermatitis or plaque-type psoriasis were treated once daily or twice daily with fluocinonide cream for 2 weeks. The most commonly observed adverse reactions in these clinical trials were as follows:

Table 1
Most Commonly Observed Adverse Reactions (≥1%) in Adult Clinical Trials

Adverse Reaction	Fluocinonide Cream, *once daily* (n=216)	Fluocinonide Cream, *twice daily* (n=227)	Vehicle Cream, *once or twice daily* (n=211)
Headache	8 (3.7%)	9 (4.0%)	6 (2.8%)
Application Site Burning	5 (2.3%)	4 (1.8%)	14 (6.6%)
Nasopharyngitis	2 (0.9%)	3 (1.3%)	3 (1.4%)
Nasal Congestion	3 (1.4%)	1 (0.4%)	0

Safety in patients 12 to 17 years of age was similar to that observed in adults.

Over Dose Effect Topically applied fluocinonide cream can be absorbed in sufficient amounts to produce systemic effects

Pregnancy Comments

Teratogenic Effects
Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Therefore, fluocinonide cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Nursing Mothers
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
Safety and efficacy of fluocinonide cream 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.
HPA axis suppression was studied in 4 sequential cohorts of pediatric patients with atopic dermatitis covering at least 20% of the body surface area, treated once daily or twice daily with fluocinonide cream. The first cohort of 31 patients (mean 36.3% BSA) 12 to < 18 years old; the second cohort included 31 patients (mean 39.0% BSA) 6 to < 12 years old; the third cohort included 30 patients (mean 34.6% BSA) 2 to < 6 years old; the fourth cohort included 31 patients (mean 40.0% BSA) 3 months to < 2 years old. Fluocinonide cream caused HPA-axis suppression in 1 patient in the twice daily group in Cohort 1, 2 patients in the twice daily group in Cohort 2, and 1 patient in the twice daily group in Cohort 3. Follow-up testing 14 days after treatment discontinuation, available for all 4 suppressed patients, demonstrated a normally responsive HPA axis. Signs of skin atrophy were present at baseline and severity was not determined making it difficult to assess local skin safety. Therefore, the safety of fluocinonide cream in patients younger than 12 years of age has not been demonstrated.
HPA axis suppression has not been evaluated in patients with psoriasis who are less than 18 years of age.
Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA-axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

HPA-axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to cosyntropin (ACTH1-24) stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric Use

Clinical studies of fluocinonide cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Section 3: Composition / information on ingredients

Each gram contains:	Active: Each gram of fluocinonide cream, USP contains 1 mg micronized fluocinonide in a cream base

Section 4: First -aid measures

General	Not Available.
Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms and effects, both acute and delayed	Irritation of eyes and mucous membranes.
Indication of any immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Acute toxicity following overdose is uncommon. Gastrointestinal decontamination is generally not necessary.

Section 5: Fire -fighting measures

Extinguishing media **Suitable extinguishing Media**	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
Unsuitable extinguishing Media	None known.
Special hazards arising from the substance or mixture	No unusual fire or explosion hazards noted.
Advice for firefighters **Special protective equipment for firefighters**	Wear suitable protective equipment.
Special fire fighting Procedures	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and material for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Precautions for Safe Handling:	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
Storage Conditions	Store at controlled room temperature: 15°C to 30°C (59°F to 86°F). Keep the tube tightly closed.

Section 8: Exposure controls/personal protection

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

Appropriate engineering Controls Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Eye/Face Protection: Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other: For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Section 9: Physical and chemical properties

Colour	White.
Physical State (liquid/solid/gas):	Semi-solid
Odour	Not available.
Odour threshold	Not available.
pH	Not applicable.
Melting point/freezing point	Not available.

Section 10: Stability and reactivity

Reactivity:	No reactivity hazards known.
Chemical Stability:	Material is stable under normal conditions.
Possibility of Hazardous Reactions:	No dangerous reaction known under conditions of normal use.
Conditions to Avoid:	None known.
Incompatible Materials:	Strong oxidizing agents.
Hazardous Decomposition Products:	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological information

Information on Likely Routes of Exposure

Ingestion Fatal if swallowed.
Inhalation Due to lack of data the classification is not possible.
Skin contact Due to lack of data the classification is not possible.
Eye contact Causes serious eye irritation.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:
Corticosteroids: Nausea. Vomiting. Headache. Acne. Increased hair growth. Lightheadedness. Weakness. Increased sweating. Eye pain. Vision changes. Mental or behavioral changes. Swelling. Numbness. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Bone fractures. Back pain. Joint pain or stiffness. Increased appetite. Redistribution of body fat. Menstrual irregularities. Impotence. Tremors.
Chronic Effects: Causes damage to organs through prolonged or repeated exposure. Adrenal suppression. Immune system suppression. Hypercorticism or Cushing's syndrome. Withdrawal effects include fever, muscle pain, joint pain, and malaise.
Cross Sensitivity: Persons sensitive to one corticosteroid may be sensitive to this material also.
Medical Conditions Aggravated By Exposure: Corticosteroids: Heart disease. High blood pressure. Diabetes. Epilepsy. Glaucoma. Hypothyroidism. Osteoporosis. Peptic ulcer. Systemic fungal infection. Mental disorders. Impaired liver or kidney function.
Acute Toxicity: Fatal if swallowed.

Product	Species	Test Results
Fluocinonide (CAS 356-12-7)		
Oral		
LD50	Mouse	> 6000 mg/kg
	Rat	14 mg/kg

Skin Corrosion/Irritation: Due to lack of data the classification is not possible.
Serious Eye Damage/Eye Irritation: Causes serious eye irritation.
Respiratory Sensitization: Due to lack of data the classification is not possible.
Skin Sensitization: Due to lack of data the classification is not possible.
Sensitization: Sensitization test Result: Negative. Species: Guinea pig
Germ Cell Mutagenicity: Data from germ cell mutagenicity tests were not found. Due to lack of data the classification is not possible.
Mutagenicity: Ames test Result: Negative.
In vitro chromosomal aberration assay (human lymphocytes) Result: Negative.
In vivo mouse micronucleus assay Result: Positive for clastogenic potential.

Carcinogenicity: Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Section 12: Ecological information

Ecotoxicity: No ecotoxicity data noted for the ingredient(s).
Persistence and Degradability: No data is available on the degradability of this product.
Bioaccumulative Potential: Not available.
Mobility in Soil: Not available.
Other Adverse Effects: Not available.

Section 13: Disposal consideration

Disposal Instructions: Dispose of contents/container in accordance with local/regional/national/international regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local Disposal Regulations: Not available.
Hazardous Waste Code: Not available.
Waste from Residues Unused Products: Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated Packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14: Transport information

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.
TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.
INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.
INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

Section 15: Regulatory information

Generic Medicine. NDC no.: 72578-087-06 (30 gm), 72578-082-02 (60 gm), 72578-087-07 (120 gm)

Section 16: Other information

None

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

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