Safety Data Sheet
Desoximetasone Cream USP
Strength: 0.25% **Pack Size:** 30 gm, 60 gm, 100 gm **NDC** 72578-091-01, 72578-091-02, 72578-091-03 **Revision No.:** 00

Emergency Overview

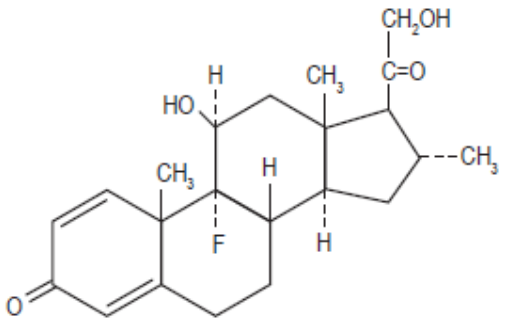
Desoximetasone Cream USP, 0.25% contains the active synthetic corticosteroid desoximetasone, USP. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and anti-pruritic agents.

Section 1 : Identification

Product Name: Desoximetasone Cream USP, 0.25%

Formula: $C_{22}H_{29}FO_4$

Chemical Name: Pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16-methyl-,(11β,16α)-



Molecular Weight: 376.47 g/mol

Description: Desoximetasone Cream USP, 0.25% contains the active synthetic corticosteroid desoximetasone, USP. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and anti-pruritic agents.

Dosage forms and strengths: Each gram of desoximetasone cream USP, 0.25% contains 2.5 mg of desoximetasone, USP in an emollient cream base consisting of cetostearyl alcohol, edetate disodium dihydrate, isopropyl myristate, lanolin alcohols, mineral oil, purified water and white petrolatum.

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	Desoximetasone cream, 0.25% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Restriction on Use / Contraindications	• Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

Section 2 : Hazard (s) Identification

Dose and Administration	Apply a thin film of desoximetasone cream, 0.25% to the affected skin areas twice daily. Rub in gently.
Adverse effects	The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: 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. In controlled clinical studies the incidence of adverse reactions was low (0.8%) for desoximetasone cream, 0.25% and included burning, folliculitis, and folliculo-pustular lesions. The incidence of adverse reactions was also 0.8% for desoximetasone cream, 0.05% and included pruritus, erythema, vesiculation, and burning sensation.
Over Dose Effect	Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects
Pregnancy Comments	***Teratogenic Effects*** *Pregnancy Category C* 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. Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration in doses 3 to 30 times the human dose of desoximetasone cream, 0.25% and 15 to 150 times the human dose of desoximetasone cream, 0.05%, or desoximetasone gel, 0.05%. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, desoximetasone cream, 0.25% 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** 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
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.
HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.
Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

Section 3: Composition / information on ingredients

Each gram contains: Each gram of desoximetasone cream USP, 0.25% contains 2.5 mg of desoximetasone, USP in an emollient cream base consisting of cetostearyl alcohol, edetate disodium dihydrate, isopropyl myristate, lanolin alcohols, mineral oil, purified water and white petrolatum.

Section 4: First -aid measures

Inhalation	If vapors of this product are inhaled, causing irritation, remove victim t fresh air. If necessary, use artificial respiration to support vital function
Ingestion:	If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never ind vomiting or give diluents (milk or water) to someone who is unconscio having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	Pre-existing skin conditions may be aggravated by repeated overexposures to this product.
RECOMMENDATIONS TO PHYSICIANS:	This product should only be given to patients by persons experienced i management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

Section 5: Fire -fighting measures

Flash point:	> 60°C (140°F)
Autoignition temperature:	Not established.
Flammable limits (in air by volume, %)	Not established.
Fire extinguishing media:	In the event of a fire, use suppression media for surrounding materials (e.g., water spray, dry chemical, carbon dioxide, foam, any "ABC" class extinguisher).
Special fire and explosion hazards:	This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and hydrogen fluoride)
Special fire-fighting procedures:	Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

Section 6: Accidental Release Measures

SPILL AND LEAK RESPONSE:

Proper protective equipment should be used. In the event of a spill, clear the area and protect people. Eliminate all sources of ignition before cleanup begins. Use non-sparking tools. Monitor area for combustible vapor levels to determine level of combustible vapors before personnel are allowed into the spill area. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA).

Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit**.** The dispersal of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such.

Section 7: Handling and Storage

WORK PRACTICES AND HYGIENE PRACTICES:

As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Avoid breathing vapors generated by this product. Use in a well-ventilated location. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

STORAGE AND HANDLING PRACTICES:

Employees must be trained to properly use this product. Keep away from heat, sparks, and other sources of ignition. Use non-sparking tools. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container. Storage areas should be made of fire resistant materials. Post warning and "NO SMOKING" signs in storage and use areas, as appropriate. Have appropriate extinguishing equipment in the storage area (i.e., sprinkler system, portable fire extinguishers). Empty packages may contain residual liquid or vapors that are flammable; therefore, empty packages should be handled with care.

Storage Conditions

Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]

Keep this and all medications out of the reach of children.

Call your doctor for medical advice about side effects.

Section 8: Exposure controls/personal protection

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures.

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	IDLH mg/m³	mg/m³
Desoximetasone	382-67-2	NE	NE	NE	NE	NE	NE	NE	NE
Cetostearyl Alcohol	36653-82-4	NE	NE	NE	NE	NE	NE	NE	NE
Isopropyl Myristate	110-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Lanolin Alcohols	8027-33-6	NE	NE	NE	NE	NE	NE	NE	NE
White Petrolatum	8009-03-8	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Terms Used.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard

EYE PROTECTION: Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or Canadian CSA Standard Z94.3-07.

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate standards of Canada.

BODY PROTECTION: During patient administration, use of lightweight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136 and the Canadian CSA Standard Z195-02, Protective Footwear.

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/CHEMICAL STABILITY:	Product is stable under normal conditions.
DECOMPOSITION PRODUCTS:	Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides and hydrogen fluoride). Hydrolysis: None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:	This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.
HAZARDOUS POLYMERIZATION:	Will not occur.
CONDITIONS TO AVOID:	Avoid heat, light, and contact with incompatible chemicals.

Section 11: Toxicological information

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Although unlikely due to form of product, inhalation of vapors of this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Skin contact may cause burning sensation, stinging, prickling, itching, and tingling. Corticosteroids (such as Desoximetasone) may cause allergic contact dermatitis. This is usually diagnosed by observing a failure to heal rather than a clinical exacerbation. Eye contact can cause irritation, stinging, redness, and tearing.

SKIN ABSORPTION: The Desoximetasone component of this product can be absorbed through intact skin. Symptoms of chronic overexposure by this route may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea.

INJECTION: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for “General Toxicity Information”.

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing the Desoximetasone component of this product or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following.

For Males and Females: Persons using the product in therapeutic doses may experience burning, itching, irritation, dryness, inflammation of hair follicles, excessive growth of hair, acne-form eruptions, diminished pigmentation, dermatitis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, skin atrophy, striae, and prickly heat.

Section 12: Ecological information

Ecotoxicity: This product has not been tested for toxicity to aquatic or terrestrial organisms; however, all release to terrestrial, atmospheric and aquatic environments should be avoided. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

Section 13: Disposal consideration

WASTE TREATMENT/DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.
U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

Section 14: Transport information

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.
TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

Section 15: Regulatory information

Generic Medicine. NDC no.: 72578-091-01 (30 gm), 72578-091-02 (60 gm), 72578-091-03 (100 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.

Date of issue: 27/08/2020 **Supersedes edition:** New Edition