Safety Data Sheet
Betamethasone Dipropionate Cream USP, 0.05%
Strength: 0.05 % **Pack Size:** 15 gm, **NDC** 70710-1233-1,
Pack Size: 45 gm **NDC** 70710-1233-4 **Revision No.:** 00

Emergency Overview

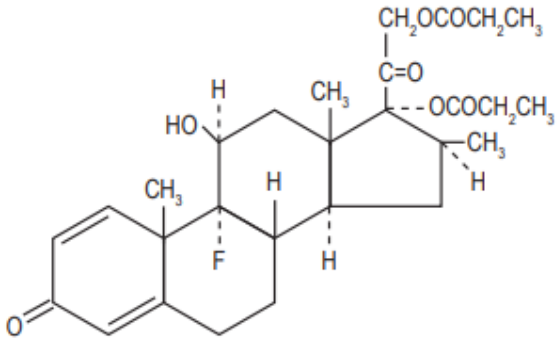
Betamethasone dipropionate cream USP, 0.05% contains betamethasone dipropionate USP, a synthetic adrenocorticosteroid, for dermatologic use. Betamethasone, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Section 1: Identification

Product Name: **Betamethasone Dipropionate Cream 0.05%**

Formula: $C_{28}H_{37}FO_7$

Chemical Name: 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate



Molecular Weight: 504.60 g/mol

Description: Betamethasone dipropionate cream USP, 0.05% contains betamethasone dipropionate USP, a synthetic adrenocorticosteroid, for dermatologic use. Betamethasone, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Dosage forms and strengths: Apply a thin film of betamethasone dipropionate cream to the affected skin areas once daily. In some cases, twice daily dosage may be necessary. If an infection develops, appropriate antimicrobial therapy should be instituted. Betamethasone dipropionate products should not be used with occlusive dressings. And, available in two packs 15 gm and 45 gm. Strength (0.05%).

Manufacturer / supplier identification

Company	Cadila Healthcare Ltd. Ahmedabad, India
Address	Cadila Healthcare, Ltd. Changodar (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	Topical corticosteroids are 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

General Hazards

Systemic absorption of topical corticosteroids has produced reversible hypothalamicpituitary- adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. 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 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. Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children 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 children.

Section 3: Composition / information on ingredients

Each gram contains:

Active: Each gram contains betamethasone dipropionate 0.64 mg equivalent to betamethasone, USP 0.5 mg.

Section 4: First -aid measures

General

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

Skin Exposure: If adverse skin effects occur, discontinue use. Seek medical attention.

Eye Exposure: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Inhalation: If vapors of this product is inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

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 induce vomiting or give diluents (milk or water) to someone who is unconscious, 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 in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

Signs and Symptoms

Cream is intended for topical use only under guidance of a physician. Cream is not considered hazardous under normal conditions.

Overdose Treatment

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects

Section 5: Fire -fighting measures

FLASH POINT:	Not applicable
Autoignition temperature:	Not applicable
Fire extinguishing media	Use extinguishing media appropriate for surrounding fire
Unsuitable Fire Extinguishing Media	None known
Special Fire And Explosion Hazards	If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and hydrogen fluoride). *Explosion Sensitivity to Mechanical Impact:* Not sensitive. *Explosion Sensitivity to Static Discharge:* Not sensitive.
Advice to fire-fighters:	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. 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. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.** Absorb spilled liquid using polypads or other suitable absorbent material. Prevent material from entering sewer or confined spaces, waterways, soil or public waters.

	Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures.

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. 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. 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.
Product Preparation Instructions For Medical Personnel	Handle this material following standard medical practices and following the recommendations presented on the Package Insert.
Specific Use(S)	This product is a human pharmaceutical. Follow all industry standards for use of this product.
Protective Practices During Maintenance Of Contaminated Equipment	When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and dispose of according to applicable U.S. Federal, State, and local hazardous waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

Section 8: Exposure controls/personal protection

Ventilation and engineering controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the appropriate equipment recommended in MSDS.

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
Betamethasone Dipropionate	5593-20-4	NE	NE	NE	NE	NE	NE	NE	NE
Cetostearyl Alcohol	67762-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Chlorocresol	59-50-7	NE	NE	NE	NE	NE	NE	NE	DFG MAK: Danger of sensitization of the skin
Mineral Oil	8012-95-1	5 (inhalable fraction)	NE	NE	NE	NE	NE	NE	NE
PEG 1000 Monocetyl Ether	9004-95-9	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-face piece pressure/demand SCBA or a full face piece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

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

Boiling point: Not established

Freezing/melting point Not established

Evaporation Rate (nBuAc = 1) Not established

Solubility in water:	Soluble.
Odor threshold:	Not established.
pH:	Not established.
Coefficient water/oil distribution:	Not established.
Appearance and color:	This product is a white, odorless, opaque cream.
How to detect this substance (warning properties):	The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.

Section 10: Stability and reactivity

Reactivity/chemical stability	This product is expected to be stable
Conditions to avoid	Avoid heat, light, and contact with incompatible chemicals.
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

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 Betamethasone Dipropionate) 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 Betamethasone Dipropionate 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 "Other Potential Health Effects".
General toxicity information	Individuals who have had allergic reactions to products containing the Betamethasone Dipropionate component of this product or any other components of this product may experience allergic reactions to this product. Persons using the product in therapeutic doses may experience stinging, elevated dark red blotches on the skin, bruising, skin shininess, burning, itching, irritation, dryness, inflammation of hair follicles, excessive hair growth, acne-form eruptions, diminished pigmentation, dermatitis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, striae, and prickly heat.
Irritancy of product	This product may mildly to moderately irritate contaminated tissue.
Sensitization of product	Corticosteroids (such as Betamethasone Dipropionate) may cause allergic contact dermatitis. The Chlorocresol component of this product can cause allergic contact dermatitis. Rarely, the Cetostearyl Alcohol component of this product can cause allergic skin reaction with hives.
Health effects or risks from exposure: an explanation in lay terms.	Overexposure to this product may cause the following health effects: Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Accidental ingestion may be harmful. Although unlikely, inhalation can irritate the respiratory system. Eye contact will cause irritation. Chronic: Corticosteroids (such as Betamethasone Dipropionate) may cause allergic contact dermatitis. Symptoms of chronic skin absorption exposure 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.
Target organs	Acute: Occupational Exposure: Skin, eyes. Therapeutic Doses: Skin. Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin, endocrine system.
Toxicity data	Only toxicity data available for the active component of this product are presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS; Contact Fougera for more information.

Section 12: Ecological information

Mobility	This product has not been tested for soil absorption or mobility.
Persistence And Biodegradability	This product has not been tested for persistence or biodegradability.
Bioaccumulation	This product has not been tested for bioconcentration.
Ecotoxicity	No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities.
Environmental exposure controls	Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.
Other Adverse Effects	No component of this product is known to have ozone depletion potential

Section 13: Disposal consideration

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

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

Section 15: Regulatory information

Generic Medicine. NDC no- 0168-0055-15; 0168-0055-46

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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