

Safety Data Sheet

Betamethasone Dipropionate Ointment, USP

Strength: 0.05%

Pack Size: 15 gm,
45 gm

NDC 72578-093-01,
72578-093-06

Revision No.: 00

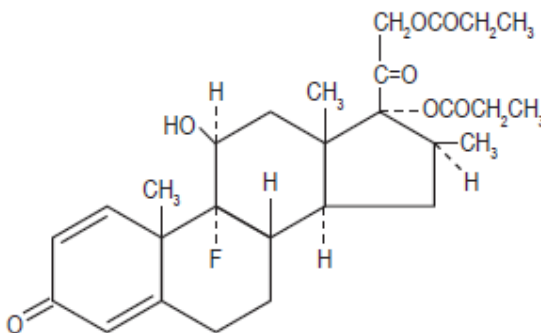
Emergency Overview

Betamethasone dipropionate ointment 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. For dermatologic use only. Not for ophthalmic use.

Section 1 : Identification

Product Name: Betamethasone Dipropionate Ointment, USP
Formula: Betamethasone Dipropionate USP: $C_{28}H_{37}FO_{17}$
Chemical Name: Betamethasone Dipropionate USP:

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



Molecular Weight: 504.60 g/mol

Description: Betamethasone dipropionate ointment 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. Betamethasone dipropionate is a white to cream white odorless powder. It is practically insoluble in water, sparingly soluble in ethanol (96%) and freely soluble in acetone, in methylene chloride and in chloroform.

Dosage forms and strengths: Apply a thin film of betamethasone dipropionate ointment 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.

Manufacturer identification

Company Address Cadila Healthcare Ltd. Ahmedabad, India
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

Safety Data Sheet

Betamethasone Dipropionate Ointment, USP

Strength: 0.05%

Pack Size: 15 gm,
45 gm

NDC 72578-093-01,
72578-093-06

Revision No.: 00

Recommended use / Therapeutic Category

Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions. 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

Dose and Administration

Apply a thin film of betamethasone dipropionate ointment 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.

Adverse effects

The following local adverse reactions are reported infrequently when betamethasone dipropionate products are used as recommended in the **DOSAGE AND ADMINISTRATION** section. 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 infections, skin atrophy, striae and miliaria.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria in some patients.

Over Dose Effect

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

Pregnancy Comments

Teratogenic Effects:

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.

Safety Data Sheet**Betamethasone Dipropionate Ointment, USP****Strength: 0.05%****Pack Size:** 15 gm,
45 gm**NDC** 72578-093-01,
72578-093-06**Revision No.:** 00**Pregnancy Comments****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:**

Each gram of the 0.05% ointment contains 0.64 mg betamethasone dipropionate, USP (equivalent to 0.5 mg betamethasone) in an ointment base of mineral oil and white petrolatum.

Section 4: First -aid measures**Inhalation**

Move to fresh air in case of accidental inhalation of vapors or decomposition products. If symptoms persist, call a physician.

Skin contact

Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.

Ingestion

Rinse mouth. Drink plenty of water. Do NOT induce vomiting. Consult a physician.

Notes to Physician

Treat symptomatically.

Protection of First-aiders

Ensure that medical personnel are aware of the material(s) involved, and take precautions protect themselves.

Safety Data Sheet

Betamethasone Dipropionate Ointment, USP

Strength: 0.05%

Pack Size: 15 gm,
45 gm

NDC 72578-093-01,
72578-093-06

Revision No.: 00

Section 5: Fire -fighting measures

Flammable properties	Not flammable
Flash Point	Not applicable
Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Explosion Data

Sensitivity to Mechanical Impact	None
Sensitivity to Static Discharge	None

Protective Equipment and Precautions for Firefighters As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NEPA	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazard 1*	Flammability 0	Physical Hazard 0	Personal Protection B

*Indicates a chronic health hazard.

Section 6: Accidental Release Measures

Personal Precautions	Use personal protective equipment. Avoid contact with the skin and the eyes.
Environmental Precautions	Refer protective measures listed in section 7 & 8.
Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Cover liquid spill with sand, earth or other noncombustible absorbent material. Pick up and transfer to properly labelled containers.

Section 7: Handling and Storage

Handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment.
Storage	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from light and freezing.

Section 8: Exposure controls/personal protection

Exposure Guidelines This product, as supplied and used, is not expected to cause exposure via inhalation unless fine aerosols or mists are generated.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
White mineral oil 8042-47-5	TWA: 5 mg/m ³ inhalable fraction excluding metal working fluids, highly & severely refined	TWA: 5 mg/m ³ (vacated) TWA: 5 mg/m ³	IDLH: 2500 mg/m ³ TWA: 5 mg/m ³ STEL: 10 mg/m ³

Engineering Measures Showers
Eyewash stations
Ventilation systems

Personal Protective Equipment
Eye/Face Protection
Skin and Body Protection
Respiratory Protection

Safety glasses with side-shields.
Protective gloves.
No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

Safety Data Sheet

Betamethasone Dipropionate Ointment, USP

Strength: 0.05%

Pack Size: 15 gm,
45 gm

NDC 72578-093-01,
72578-093-06

Revision No.: 00

Section 9: Physical and chemical properties

Colour Off-White.
Physical State (liquid/solid/gas): Semi-solid
Pack Style 15 g, 45 g.

Section 10: Stability and reactivity

Stability Stable under recommended storage conditions.
Incompatible Products Oxidizing agents. Reducing agents.
Conditions to Avoid None known.
Hazardous Decomposition Products Carbon oxides
Harardous Polymerization Hazardous polymerization does not occur.

Section 11: Toxicological information

Acute Toxicity

Product Information May cause eye and skin irritation.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Petrolatum (USP Grade)		~ 3600 mg/kg (Rabbit)	
White mineral oil	> 5000 mg/kg (Rat)	-	-
Betamethasone Dipionate	> 4 g/kg (Rat)	-	-

Chronic Toxicity

Chronic Toxicity Prolonged or repeated contact may dry skin and cause irritation.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systematically 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.

Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen. Mineral oils are known to cause cancer because of carcinogenic components (e.g. benzene). The mineral oil in this product is highly refined and should not be considered a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
White mineral oil	A2			

ACGIH: (American Conference of Governmental Industrial Hygienists)

A2 - Suspected Human Carcinogen

IARC: (International Agency for Research on Cancer)

NTP: (National Toxicity Program)

OSHA: (Occupational Safety & Health Administration)

Teratogenic Pregnancy: Teratogenic Effects: 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.

Target Organ Effects Skin. Endocrine system. Reproductive system. Contains material that may adversely affect the developing fetus. Immune system.

Safety Data Sheet

Betamethasone Dipropionate Ointment, USP

Strength: 0.05%

Pack Size: 15 gm,
45 gm

NDC 72578-093-01,
72578-093-06

Revision No.: 00

Section 12: Ecological information

Ecotoxicity

The environmental impact of this product has not been fully investigated. Ecotoxicity effects of component substances.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
White mineral oil		LC50 96 h: > 10000 mg/L (Lepomis macrochirus)		

Chemical Name	Log Pow
White mineral oil	9.006

Section 13: Disposal consideration

Waste Disposal Methods

This material, as supplies, is not a hazardous waste according to Federal Regulation (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of in accordance with local regulations. Do not re-use empty containers.

California Hazardous Waste Codes

311

California Waste Code Legend

Pharmaceutical waste

Section 14: Transport information

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG/IMO</u>	Not regulated

Section 15: Regulatory information

Generic Medicine. NDC no.: 72578-093-01 (15 gm), 72578-093-06 (45 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: 16/07/2020

Supersedes edition: New Edition