Safety Data Sheet
Desonide Cream, 0.05%
Strength: 0.05 % **Pack Size:** 15 g, 60 g **NDC** 72578-086-01, 72578-086-02 **Revision No.:** 00

Emergency Overview

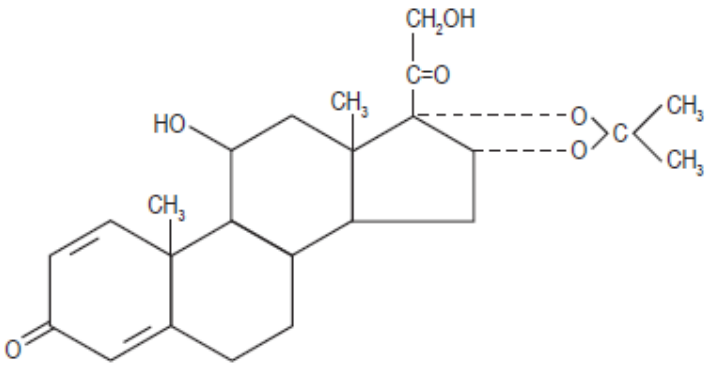
Desonide cream, 0.05% contains desonide (Pregna-1, 4-diene-3, 20-dione, 11, 21-dihydroxy-16, 17-[(1-methylethylidene)bis(oxy)]-,(11β,16α)) a synthetic corticosteroid for topical dermatologic use. The corticosteroids constitute a class of primary synthetic steroids used topically as anti-inflammatory and antipruritic agents.

Section 1 : Identification

Product Name: **Desonide Cream, 0.05%**

Formula: $C_{24}H_{32}O_6$

Chemical Name: Pregna-1, 4-diene-3, 20-dione, 11, 21-dihydroxy-16, 17-[(1-methylethylidene)bis(oxy)]-,(11β,16α).



Molecular Weight: 416.51 g/mol

Description: Desonide cream, 0.05% contains desonide (Pregna-1, 4-diene-3, 20-dione, 11, 21-dihydroxy-16, 17-[(1-methylethylidene)bis(oxy)]-,(11β,16α)) a synthetic corticosteroid for topical dermatologic use.

Dosage forms and strengths: Desonide cream, 0.05% should be applied to the affected area as a thin film two to four times daily depending on the severity of the condition.
As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within two weeks, reassessment of diagnosis may be necessary.
Desonide cream, 0.05% should not be used with occlusive dressings

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	Desonide cream, 0.05% is a low potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. It should not be used for longer than two weeks unless directed by a physician.
Restriction on Use / Contraindications	Desonide cream, 0.05% is 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	Desonide cream, 0.05% should be applied to the affected area as a thin film two to four times daily depending on the severity of the condition. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within two weeks, reassessment of diagnosis may be necessary. Desonide cream, 0.05% should not be used with occlusive dressings.
Adverse effects	In controlled clinical trials, the total incidence of adverse reactions associated with the use of desonide cream, 0.05% was approximately 1%. These adverse reactions were pruritus, pain, folliculitis, rash, peripheral edema, pustular rash, sweating, erythema, irritation, and burning. Laboratory abnormalities were found in 3% of the patients. These were hyperglycemia (2%) and liver function abnormality (1%). The following additional local adverse reactions have been reported infrequently with topical corticosteroids, and they may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in approximate decreasing order of occurrence: dryness, folliculitis, acneiform eruptions, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, miliaria, burning and hypopigmentation. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
Over Dose Effect	Topically applied desonide cream, 0.05% 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. Animal reproductive studies have not been conducted with desonide cream, 0.05%. It is also not known whether desonide cream, 0.05% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. There are no adequate and well-controlled studies in pregnant women. Desonide cream, 0.05% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Pharmacokinetics	The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Studies performed with desonide cream, 0.05% indicate that it is in the low range of potency as compared with other topical corticosteroids.

Section 3: Composition / information on ingredients

Contains: Active: Desonide (0.05%)

Section 4: First -aid measures

Eye Contact: Immediately flush eyes with water while lifting the upper and lower lids for several minutes. Get medical attention if irritation persists.

Skin Contact: This product is intended for use on the skin. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Symptoms and Effects of Exposure: May cause mild eye and skin irritation. Ingestion may cause gastrointestinal effects such as nausea or diarrhea.

Section 5: Fire -fighting measures

Extinguishing Media: Use any media that is suitable for the surrounding fire.

Hazardous Combustion Products: Product is not flammable or combustible but may burn in a fire.

Fire Fighting Procedures: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

Section 6: Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

Measures for Environmental Protections: Prevent spill from entering severs and water courses. Report releases as required by local and national authorities.

Section 7: Handling and Storage

General Handling: Avoid the generation of mists. Avoid eye contact. Avoid unintended contact with skin. Wash thoroughly with soap and water after handling.

Storage Conditions: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 8: Exposure controls/personal protection

Desonide	0.75 ug/m3 TWA (Perrigo OEL)
White Petrolatum	5 mg/m3 (inhalable) TWA ACGIH TLV 5 mg/m3 TWA OSHA PEL
Glycerin	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Beeswax	None Established
Water	None Established
Cetyl Stearyl Alcohol	None Established
Mineral Oil	5 mg/m3 (inhalable) TWA ACGIH TLV 5 mg/m3 TWA OSHA PEL
Methyl paraben	500 ug/m3 TWA (Perrigo OEL)
Sodium Lauryl Sulfate	500 ug/m3 TWA (Perrigo OEL)
Calcium Acetate	Perrigo OEB1 (1000-3000 ug/m3)
Aluminum Sulfate	1 mg/m (respirable) TWA ACGIH TLV 5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Dextrin	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Eyes: None required for normal use.

Skin: None required for normal use. Impervious gloves recommended for manufacturing operations.

Respiratory protection:	None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and Industrial hygiene practice.

Section 9: Physical and chemical properties

Physical State	White Cream
Odor	Characteristic fatty odor
Solubility	Partially soluble in water

Section 10: Stability and reactivity

Reactivity	Not reactive under normal conditions of use.
Chemical stability	Stable
Incompatible materials	Avoid oxidizing agents
Hazardous decomposition products	Thermal decomposition may yield carbon oxides.

Section 11: Toxicological information

Acute effects of exposure:

Inhalation:	Inhalation of mists may cause minor irritation of the mucous membrane of upper respiratory tract.
Ingestion:	Swallowing may cause gastrointestinal distress with nausea and diarrhea.
Skin contact:	No adverse effects are expected. Minor irritation is possible
Eye contact:	Contact may cause irritation.
Chronic effects:	None known
Sensitization:	Components are not known to be sensitizers. Allergic reactions may occur in some users.
Germ cell mutagenicity:	No adverse effects are expected. Components are not germ cell mutagens.
Reproductive Toxicity:	No adverse effects are expected. 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. Animal reproductive studies have not been conducted with Desonide.
Carcinogenicity:	None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values:

Desonide:	LD50 oral mouse 3710 mg/kg
Mineral Oil:	LD50 oral rat > 5000 mg/kg.
Petrolatum:	LD50 oral rat > 5000 mg/kg.

Section 12: Ecological information

Ecotoxicity values:	No data is available
Persistence and degradability:	No data is available
Bioaccumulative potential:	No data is available
Mobility in soil	No data is available
Other adverse effects:	None known.

Section 13: Disposal consideration

Disposal methods: Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

Section 14: Transport information

The following refers to all categories of classifications unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

DOT	Not regulated
TDG	Not regulated
IMDG	Not regulated
IATA	Not regulated

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in package form

Special precautions: Not known.

Section 15: Regulatory information

Generic Medicine. NDC no – 72578-086-01 (15 gm) and 72578-086-02 (60 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: 06/06/2020 **Supersedes edition:** Not applicable