Safety Data Sheet
Clobetasol Propionate Lotion
Strength: 0.05% **Pack Size:** 59 ml, 118 ml **NDC** 72578-085-01, 72578-085-02 **Revision No.:** 00

Emergency Overview

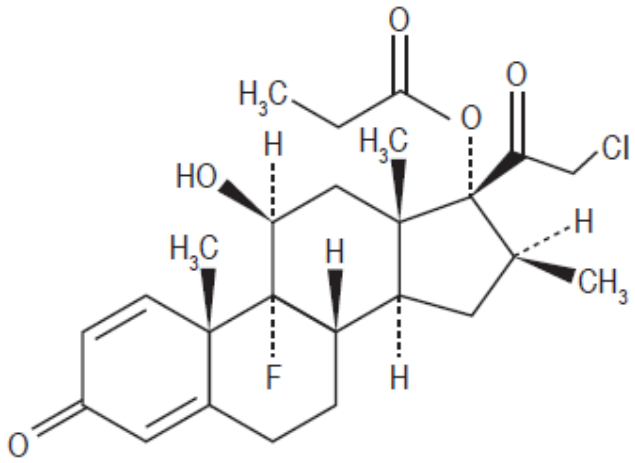
Clobetasol propionate lotion, 0.05% contains clobetasol propionate, a synthetic fluorinated corticosteroid, for topical use. The corticosteroids constitute a class of primarily synthetic steroids used topically as anti-inflammatory and antipruritic agents.

Section 1 : Identification

Product Name: Clobetasol propionate lotion, 0.05%

Formula: $C_{25}H_{32}ClFO_f$

Chemical Name: 21-chloro-9-fluoro-11β,17-dihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-propionate



Molecular Weight: 466.97 g/mol

Description: Clobetasol propionate lotion, 0.05% contains clobetasol propionate, a synthetic fluorinated corticosteroid, for topical 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 clobetasol propionate lotion, 0.05% contains 0.5 mg of clobetasol propionate, in a vehicle base contains following inactive ingredients: cetostearyl alcohol, glycerol monostearate and polyethylene glycol-75 palmitostearate, glyceryl stearate/polyethylene glycol-100 stearate, mineral oil, polyoxyethylene glycol 300 isostearate, propylene glycol and purified water.

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.

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Emergency Telephone No	Tel.:+91 2717-616401
Recommended use / Therapeutic Category	Clobetasol propionate lotion, 0.05% is a super-high potent topical corticosteroid formulation indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses only in patients 18 years of age or older. Treatment should be limited to 2 consecutive weeks. For moderate to severe plaque psoriasis, treatment may be extended for an additional 2 weeks for localized lesions (less than 10% body surface area) that have not sufficiently improved after the initial 2 week treatment. Any additional benefits of extending treatment should be weighed against the risk of hypothalamic-pituitary-adrenal (HPA) axis suppression before prescribing for more than 2 weeks. The total dosage should not exceed 50 g (50 mL or 1.75 fl. oz) per week. Patients should be instructed to use clobetasol propionate lotion, 0.05% for the minimum amount of time necessary to achieve the desired results. Use in patients under 18 years of age is not recommended due to numerically high rates of HPA axis suppression
Restriction on Use / Contraindications	Clobetasol propionate lotion, 0.05% should not be used on the face, axillae, or groin and should not be used if there is atrophy at the treatment site. Clobetasol propionate lotion, 0.05% should not be used in the treatment of rosacea or perioral dermatitis.

Section 2 : Hazard (s) Identification

Dose and Administration	Clobetasol propionate lotion, 0.05% is for topical use only, and not for ophthalmic, oral or intravaginal use. Clobetasol propionate lotion, 0.05% should be applied to the affected skin areas twice daily and rubbed in gently and completely. The total dosage should not exceed 50 g (50 mL or 1.75 fl. oz.) per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Clobetasol propionate lotion, 0.05% contains a topical corticosteroid; therefore treatment should be limited to 2 consecutive weeks for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and up to 2 additional weeks in localized lesions (less than 10% body surface area) of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment with clobetasol propionate lotion, 0.05%. Unless directed by physician, clobetasol propionate lotion, 0.05% should not be used with occlusive dressings.

Adverse effects

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.
In controlled, clinical trials with clobetasol propionate lotion, 0.05%, the following adverse reactions have been reported: burning/stinging, skin dryness, irritation, erythema, folliculitis, pruritus, skin atrophy, and telangiectasia. The pooled incidence of local adverse reactions in trials for psoriasis and atopic dermatitis with clobetasol propionate lotion, 0.05% at 1% or greater was:

Adverse Reactions with Incidence ≥ 1% in Clinical Trials

Adverse Reaction	**Incidence**
Skin Atrophy	4.2%
Telangiectasia	3.2%
Discomfort Skin	1.3%
Skin Dry	1%

Most local adverse events were rated as mild to moderate and they are not affected by age, race or gender.
Systemic absorption of topical corticosteroids has produced hypothalamic–pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Post-marketing Experience
Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
The following adverse reactions have been identified during post-approval use of clobetasol propionate lotion, 0.05%.
• *Endocrine disorders:* Cushing's syndrome, Adrenal suppression
• *Skin:* Rash, Pain of skin, Skin exfoliation, Skin chapped, Scaling, Induration/papulation, Lichenification.
• *Other:* Psoriasis (aggravation), Plaque elevation, Excoriation.

Over Dose Effect

Topically applied clobetasol propionate lotion, 0.05% can be absorbed in sufficient amount to produce systemic effects

Pregnancy Comments

Teratogenic Effects: Pregnancy Category C:

There are no adequate and well-controlled studies in pregnant women. Therefore, clobetasol propionate lotion, 0.05% 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 to laboratory animals.

Clobetasol propionate is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and the mouse.

Clobetasol propionate has greater teratogenic potential than steroids that are less potent.

The effect of clobetasol propionate on pregnancy outcome and development of offspring was studied in the rat. Clobetasol propionate was administered subcutaneously to female rats twice daily (0, 12.5, 25, and 50 mcg/kg/day) from day 7 of presumed gestation through day 25 of lactation or day 24 presumed gestation for those rats that did not deliver a litter. The maternal no-observed-effect level (NOEL) for clobetasol propionate was less than 12.5 mcg/kg/day due to reduced body weight gain and feed consumption during the gestation period. The reproductive NOEL in the dams was 25 mcg/kg/day (ratio of animal dose to proposed human dose of 0.07 on a mg/m2/day basis) based on prolonged delivery at a higher dose level. The no-observed-adverse-effect-level (NOAEL) for viability and growth in the offspring was 12.5 mcg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m2/day basis) based on incidence of stillbirths, reductions in pup body weights on days 1 and 7 of lactation, increased pup mortality, increases in the incidence of umbilical hernia, and increases in the incidence of pups with cysts on the kidney at higher dose levels during the preweaning period. The weights of the epididymides and testes were significantly reduced at higher dosages. Despite these changes, there were no effects on the mating and fertility of the offspring.

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. Because many drugs are excreted in human milk, caution should be exercised when clobetasol propionate lotion, 0.05% is administered to a nursing woman.

Pediatric Use

Use of clobetasol propionate lotion, 0.05% in pediatric patients is not recommended due to the potential for HPA axis suppression [*see Warnings and Precautions (5.1)*].

The HPA axis suppression potential of clobetasol propionate lotion, 0.05% has been studied in adolescents (12 to 17 years of age) with moderate to severe atopic dermatitis covering a minimum of 20% of the total body surface area. In total 14 subjects were evaluated for HPA axis function. Subjects were treated twice daily for 2 weeks with clobetasol propionate lotion, 0.05%. After 2 weeks of treatment, 9 out of 14 of the subjects experienced adrenal suppression. One out of 4 subjects treated with clobetasol propionate lotion, 0.05% who were retested remained suppressed two weeks post-treatment. In comparison, 2 of 10 subjects treated with clobetasol propionate cream, 0.05% demonstrated HPA axis suppression. One subject who was retested recovered.

None of the subjects who developed HPA axis suppression had concomitant clinical signs of adrenal suppression and none of them was discontinued from the study for reasons related to the safety or tolerability of clobetasol propionate lotion, 0.05%. However patients with acute illness or injury may have increased morbidity and mortality with intermittent HPA axis suppression.

Because of 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 glucocorticosteroid insufficiency during and/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 ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric Use

Clinical studies of clobetasol propionate lotion, 0.05% did not include sufficient numbers of subjects aged 65 and over to adequately determine whether they respond differently than younger subjects. In general, dose selection for an elderly patient should be made with caution, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Section 3: Composition / information on ingredients

Each gram contains: Each gram of clobetasol propionate lotion, 0.05% contains 0.5 mg of clobetasol propionate, in a vehicle base contains following inactive ingredients: cetostearyl alcohol, glycerol monostearate and polyethylene glycol-75 palmitostearate, glyceryl stearate/polyethylene glycol-100 stearate, mineral oil, polyoxyethylene glycol 300 isostearate, propylene glycol and purified water.

Section 4: First -aid measures

Inhalation	No identified risk
Skin contact :	No expected risk after a single exposure.
Eye contact :	Flush eyes with plenty of water for at least 15 minutes. Hold eyelids open to ensure cleansing. In the event of persistent irritation, seek medical attention.
Ingestion :	Never give anything by mouth to an unconscious person. In the event of ingestion of Clobetasol propionate lotion, wash out the mouth. If swallowed, do not induce vomiting. Give water freely to dilute stomach contents. If vomiting occurs, keep airway clear. Call a physician.

Section 5: Fire -fighting measures

Clobetasol propionate lotion does not present any unusual or significant fire hazard. Material will burn reluctantly when exposed to an open flame.

Extinguishing media : Use extinguishing media appropriate for the surrounding fire conditions : carbonic anhydride, dry chemical powder or appropriate foam

Specific hazards : Burning may produce toxic gases.

Specific methods : No data

Protection of fire fighters : Wear self contained breathing apparatus and full body protective Equipment

Fire fighting procedures : Move containers from fire area if it can be done without risk. Use water to keep fire-exposed containers cool

Section 6: Accidental Release Measures

Personal precaution : Wear chemically compatible gloves. Avoid contact. Wash contaminated clothing before reuse.

Environmental precautions: Keep spill out of drains and prevent entry to surface water, groundwater and soil

Methods for cleaning up :

- **Recovery :** Stop leaks/spills. Vacuum or scoop spilled material. Place spillage in appropriate container(s) for waste disposal
- **Neutralisation :** Wash spill site thoroughly after material pick up is complete
- **Disposal :** Dispose in accordance with all applicable national and local environmental regulations and laws

Prevention of secondary hazards : No data

Section 7: Handling and Storage

Handling :

- **Technical measures :** Not restricted
- **Precautions :** Avoid contact with eyes. Wash thoroughly after handling
- **Safe handling advice :** Wash contaminated clothing and personal protective equipment

Storage :

- **Technical measures :** Store in well-closed containers and protected from light below 25°C
- **Storage conditions :** Protect from light. Do not permit eating, smoking or drinking in the vicinity
- **Incompatible products :** Combustible or flammable materials
- **Packaging materials :** HDPE bottles fitted with a polypropylene dispensing closure

Section 8: Exposure controls/personal protection

Engineering measures to reduce exposure :	Not applicable
Specific control parameters :	No data
Personal protective equipment :	
Respiratory protection :	Not necessary
Hand protection :	Wear rubber gloves
Eye protection :	Wear safety goggles or glasses with side shields
Skin and body protection :	Minimise exposed skin with appropriate clothing (long sleeves, chemically-resistant safety shoes etc.)
Specific hygiene measures :	Wash contaminated clothing with soap and water and dry before reuse.

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.
Hazardous reactions	None identified. Protect from light. Bases must be avoid.
Hazardous decomposition Products	No specific toxic emanations. No hazard of polymerisation

Section 11: Toxicological information

Acute toxicity :	Inhalation : n/a Ingestion : The drug substance has a low order of acute oral toxicity (> 3000 mg/kg in rats).
Local effects :	This product may produce dermal irritation upon prolonged or repeated dermal exposure. Minimal to moderate transient ocular irritation may occur following topical ocular exposure.
Sensitization :	No evidence of delayed contact hypersensitivity observed in a maximization test in Guinea pigs.
Specific effects :	Toxic effects observed in chronic toxicity studies with the active ingredient are typical of potent corticosteroids and include body weight gain depression, thymus and adrenal atrophy, lymphopenia, decreased serum corticosterone,. By the dermal route, skin thinning is observed locally. Teratogeneticity and growth retardation induction in laboratory animals when administered systemically or topically, but insufficient evidence in pregnant woman.

Section 12: Ecological information

Environmental effects, behavior and fate :

Mobility : The drug substance is insoluble in water and has no measurable vapour pressure. It is not therefore expected to be mobile, to migrate toward the aquatic compartment or to enter into the air

Persistence-Degradability : No data

Bioaccumulation : No data

Ecotoxicity : Unlikely to cause an adverse impact to the aquatic release environment. Information not yet available.

Section 13: Disposal consideration

Waste from residues : Dissolve in a combustible solvent and dispose of by incineration in an approved incinerator in accordance with applicable waste disposal regulations.

Contaminated packaging : Dissolve in a combustible solvent and dispose of by incineration in an approved incinerator in accordance with applicable waste disposal regulations.

Section 14: Transport information

International regulations : Currently, no class assigned. May be subject to national or local transportation requirements.

Section 15: Regulatory information

Generic Medicine. NDC no.: 72578-085-01 (59 ml), 72578-085-02 (118 ml)

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