PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

PrLYDERM
Fluocinonide
Ointment, Gel and Cream, USP
0.05% w/w

Topical Corticosteroids

Taropharma,
a division of Taro Pharmaceuticals Inc.
130 East Drive
Brampton, Ontario, Canada
L6T 1C3

Date of Initial Authorization:
December 8, 1997

Date of Revision:
December 5, 2023

Control #: 267880

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

LYDERM (fluocinonide) is indicated for topical therapy of corticosteroid responsive acute and chronic skin eruptions where an anti-inflammatory, anti-allergenic and anti-pruritic activity in the topical management is required.

2 CONTRAINDICATIONS

Topical corticosteroids are contraindicated in untreated bacterial, tubercular, fungal and most viral lesions of the skin (including herpes simplex, vaccinia and varicella). They are also contraindicated in individuals with a history of hypersensitivity to its components.

3 DOSAGE AND ADMINISTRATION

3.1 Recommended Dose and Dosage Adjustment

The cream is recommended for moist, weeping lesions, the ointment is suitable when an emollient effect is desired, and the gel may be more appropriate for lesions of the scalp.

A small amount of LYDERM should be applied gently on the affected skin area, two to four times daily, depending on the severity of the condition.

It is recommended that LYDERM not be used under occlusive conditions.

4 OVERDOSAGE

There is no specific antidote, but gastric lavage should be performed. In case of hypercorticism and/or adrenal suppression, discontinue therapy.

For management of a suspected drug overdose, contact your regional poison control centre.

5 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table – Dosage Forms, Strengths, Composition and Packaging.

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Topical	Ointment 0.05 % w/w	Glyceryl Monostearate, Propylene Carbonate, Propylene Glycol White Petrolatum, , and White Wax
	Gel 0.05 % w/w	Carbomer, Edetate Disodium, Propylene Glycol, Propyl Gallate, Purified Water, and Sodium Hydroxide
	Cream 0.05 % w/w	Citric Acid, Glycerin, 1,2,6-hexanetriol, Polyethylene Glycol 3350, Polyethylene Glycol 8000, Propylene Glycol, and Stearyl Alcohol

LYDERM (Fluocinonide) Cream, Ointment, and Gel is available in 15 g and 60g collapsible tubes. LYDERM (Fluocinonide) Cream is also available in 400 g plastic jars.

Ointment
The ointment base provides for optimal release of fluocinonide while retaining the occlusive and emollient effects desirable in an ointment.

The components of the cream and ointment base do not hydrolyze, deteriorate, become rancid, or support mold growth. The active ingredient is totally in solution; no undissolved solid corticosteroid particles are present. These formulations do not contain Lanolin, Parabens or Phenolic compounds.

Gel
This clear, colorless, thixotropic vehicle is greaseless, non-staining and completely water miscible. In this formulation, the active ingredient is totally in solution. The gel does not contain Lanolin, Parabens or Phenolic compounds.

Cream
This white cream vehicle is greaseless, non-staining, anhydrous and completely water miscible. While the base provides excellent emollient and hydrophilic properties, it is also designed for optimal release of the active ingredient.

6 WARNINGS AND PRECAUTIONS

6.1 General
Patients should be advised to inform subsequent physicians of the prior use of corticosteroids. Significant systemic absorption may result when steroids are applied over large areas of the body. To minimize the possibility, when long-term therapy is anticipated, interrupt treatment periodically or treat one area of the body at a time. If a symptomatic response is not noted within a few days to a week, the local application of corticosteroids should be discontinued, and the patient re-evaluated.

6.2 Endocrine and Metabolism
Systemic effects of topical corticosteroids may include reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment with the topical corticosteroid.

Because of the potential for systemic absorption, use of topical corticosteroids, including LYDERM Cream, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent corticosteroids, use over large surface areas, occlusive use, and use on an altered skin barrier, concomitant use of multiple corticosteroid-containing products, liver failure, and young age.

If HPA axis suppression is documented, attempt to gradually withdraw the drug, reduce the frequency of application, or substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Pediatric patients may be more susceptible than adults to systemic toxicity from the use of topical corticosteroids due to their larger surface-to-body mass ratios.

6.3 Ophthalmic
These products are not for ophthalmic use.

Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported in post-marketing experience with the use of topical corticosteroid products. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

Apply cautiously on lesions close to the eye. Severe irritation is possible if these formulations contact the eye. Should this occur, immediate flushing of the eye with a large volume of water is recommended.

6.4 Hepatic
As corticosteroids undergo hepatic metabolism, LYDERM should be used with caution in patients with hepatic impairment.

6.5 Immune
Hypersensitivity reactions have been rare been observed with topically applied steroid products.

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Consider confirmation of a clinical diagnosis of allergic contact dermatitis by appropriate patch testing. Discontinue LYDERM if allergic contact dermatitis occurs.

6.6 Infections
During the use of topical corticosteroids secondary infections may occur.

In cases of bacterial infections of the skin, appropriate antibacterial agents should be used as primary therapy. If it is considered necessary, the topical corticosteroid product may be used as an adjunct to control inflammation, erythema and itching. If a favorable response to an appropriate antimicrobial agent does not occur promptly, discontinue use of LYDERM (Fluocinonide) until the infection has been adequately treated.

6.7 Skin
Prolonged use of topical corticosteroid products may produce atrophy of the skin and of subcutaneous tissues, particularly on flexor surfaces and on the face. If this is noted, discontinue the use of this product.

Topical corticosteroids should be used with caution in patients with stasis dermatitis and other skin diseases associated with impaired circulation.

These products are not recommended for use under occlusive dressings.

6.8 Special Populations

6.8.1 Pregnancy and Lactation
The safety of topical corticosteroids during pregnancy or lactation has not been established. There are no available data on fluocinonide use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk.

There are no data on the presence of fluocinonide or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production after treatment with fluocinonide.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LYDERM.

Advise breastfeeding women not to apply LYDERM directly to the nipple and areola to avoid direct infant exposure.

The potential benefit of topical corticosteroids, if used during pregnancy or lactation, should be weighed against possible hazard to the fetus or the nursing infant.

6.8.2 Pediatrics
Safety and effectiveness of fluocinonide in pediatric patients under the age of 18 years have not been evaluated.

Because of higher skin surface area to body mass ratios, 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 adrenal insufficiency during or after withdrawal of treatment. Adverse reactions including striae have been reported with use of topical corticosteroids in infants and children (see WARNINGS AND PRECAUTIONS, Endocrine and Metabolism).

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 an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

6.8.3 Geriatrics
A limited number of subjects aged ≥ 65 years have been treated with fluocinonide in clinical trials, therefore the safety and efficacy have not been established in this patient population.

6.9 Laboratory Tests
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 plasma cortisol, and urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

7 ADVERSE REACTIONS

7.1 Adverse Reaction Overview
The following adverse skin reactions have been reported with the use of topical corticosteroids: dryness, burning, itching, local irritation, folliculitis, acneiform eruptions, striae, skin atrophy, atrophy of subcutaneous tissues, perioral dermatitis, telangiectasia, allergic contact dermatitis, leukoderma, maceration of the skin, hypertrichosis, change in pigmentation and secondary infection. Adrenal suppression has also been reported following topical corticosteroid therapy. Posterior subcapsular cataracts have been reported following systemic use of corticosteroids.

Systemic absorption of corticosteroids has produced manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Hypertension and gastroenteritis, although uncommon, has been observed. In rare instances, treatment (or withdrawal of treatment) of psoriasis with corticosteroids is thought to have provoked the pustular form of the disease.

7.2 Post-Market Adverse Reactions

The following adverse skin reactions have been reported with the use of topical corticosteroids and may occur more frequently with potent corticosteroids such as LYDERM (Fluocinonide) cream. These reactions are listed in an approximately 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. Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. In rare instances, treatment (or withdrawal of treatment) of psoriasis with corticosteroids is thought to have provoked the pustular form of the disease.

8 DRUG INTERACTIONS

8.1 Overview
No formal drug-drug interaction studies were conducted with Fluocinonide.

9 ACTION AND CLINICAL PHARMACOLOGY

9.1 Mechanism of Action
Fuocinonide possess anti-inflammatory, anti-pruritic and vasoconstrictor actions.

10 STORAGE, STABILITY AND DISPOSAL

LYDERM (Flucinonide) should be stored at room temperature (15°C - 30°C).

PART II: SCIENTIFIC INFORMATION

11 PHARMACEUTICAL INFORMATION

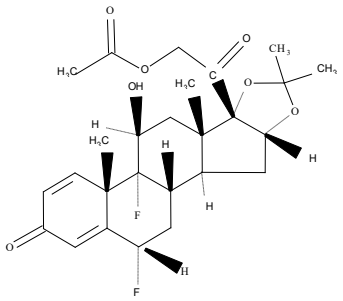
Drug Substance

Proper name: Fluocinonide

Chemical Name: Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-6,9-difluoro-11-hydroxy-16,17-[(1-methylethylidene)bis(oxy)]-,(6α,11β,16α)-

6α,9-Difluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione, cyclic 16,17-acetal with acetone, 21-acetate
[*356-12-7*]

Structural Formula:



Molecular Formula: $C_{26}H_{32}F_2O_7$

Molecular Mass: 494.53 g/mol

Physicochemical properties

Description: Fluocinonide is a white to creamy white, practically odorless, crystalline powder.

Melting Point: Melts at about 300°C with decomposition.

Solubility: It is sparingly soluble in acetone and chloroform, slightly soluble in ethanol and methanol, very slightly soluble in ether and practically insoluble in water.

12 CLINICAL TRIALS

12.1 Study Results

Gel

Seven investigators compared the gel 0.05% with a placebo gel for safety and efficacy in symmetric paired lesions diagnosed as atopic dermatitis or psoriasis in 70 patients. Two other investigators have evaluated the efficacy, safety, and cosmetic acceptability of gel 0.05% in the treatment of scalp psoriasis. The study was conducted double-blind with 39 patients randomly receiving either the gel or the placebo gel. The data from these studies shows statistically significant superiority of the gel 0.05% over the placebo gel for all three indications.

Cream and Ointment

Forty-seven investigators completed a large-scale double-blind, paired comparison clinical trial utilizing a common protocol. Seven hundred and seventeen patients were studied on the cream formulation, and 731 patients on the ointment formulation.

The results of these studies were analyzed statistically utilizing both the truncated sequential method and the student t-tests. Fluocinonide in the cream and ointment formulation, when tested in steroid-responsive dermatoses, gave significant therapeutic results. The low incidence and mild severity of adverse reactions noted by the patients and the investigators indicate that the drug is safe and effective when used as directed.

Similar results have been reported with fluocinonide solution 0.05%. In four double blind, randomized, placebo comparison trials involving 444 patients, over 200 of whom received fluocinonide solution; fluocinonide was found to be safe and effective. The side effects reported in these trials were similar to those reported by patients using the cream and ointment formulations. No unusual or serious adverse reactions were noted.

Comparative Studies

A one-period, randomized, study was performed on 40 pre-screened, asymptomatic, female subjects to compare the vasoristriction response of LYDERM Ointment 0.05% manufactured by Taro Pharmaceuticals Inc. with LIDEX® Ointment manufactured by Syntex, Canada. The degree of vasoconstriction was determined both by visual assessment and with a chromameter. Results based on visual evaluation and chromameter response indicated *in vivo* equivalence betweenLYDERM Ointment and LIDEX® Ointment.

Table 1: Mean Results for Visual and Chromameter Evaluation of LYDERM Ointment vs. LIDEX® Ointment using Locke's Method for calculating confidence intervals:

LYDERM Ointment vs. LIDEX® Ointment	N	Means		Ratio (%)[3]	90% Confidence Interval[4]	
		Test[1]	Reference[2]		Lower (%)	Upper (%)
Visual	35	17.20	17.81	96.6	88.5	105.7
Chromameter	29	15.28	13.60	112.4	88.6	136.8

[1] Test: LYDERM Ointment, 0.05% (Taro Pharmaceuticals Inc.)
[2] Reference: LIDEX® Ointment, 0.05% (Syntex, Canada)
[3] Ratio calculated as Test mean divided by the Reference mean, expressed as a percentage
[4] Confidence interval on the ratio

A one-period, randomized, study was performed on 40 pre-screened, asymptomatic, female subjects to compare the vasoconstriction response of LYDERM Gel 0.05% manufactured by Taro Pharmaceuticals Inc., with TOPSYN® Gel 0.05% manufactured by Syntex, Canada. The degree of vasoconstriction was determined both by visual assessment and with a chromameter. Results based on visual evaluation and chromameter response indicated *in vivo* equivalence between LYDERM Gel and TOPSYN® Gel.

Table 2: Mean Results for Visual and Chromameter Evaluation of LYDERM Gel vs. TOPSYN® Gel using Locke's Method for calculating confidence intervals:

LYDERM Gel vs. TOPSYN® Gel	N	Means		Ratio (%)[3]	90% Confidence Interval[4]	
		Test[1]	Reference[2]		Lower (%)	Upper (%)
Visual	22	35.74	37.63	95.0	91.1	99.1
Chromameter	26	30.52	30.47	100.2	90.2	111.2

[1] Test: LYDERM Gel, 0.05% (Taro Pharmaceuticals Inc.)
[2] Reference: TOPSYN® Gel, 0.05% (Syntex, Canada)
[3] Ratio calculated as Test mean divided by the Reference mean, expressed as a percentage.
[4] Confidence interval on the ratio.

13 DETAILED PHARMACOLOGY

Fluocinonide demonstrated 310 and 160 times the subcutaneous and oral thymolytic activity of cortisol respectively. Its anti-granuloma activity in relation to cortisol was of the same magnitude as its thymolytic activity. The composite results of seven assays demonstrates that fluocinonide has 350 times the topical anti-inflammatory activity of cortisol when tested utilizing the croton oil-inflamed ear. The glucocorticoid activity of fluocinonide to cortisol was determined in adrenalectomized male rats. The results demonstrate that fluocinonide has approximately 50 times the glucocorticoid activity of cortisol.

Fluocinonide has approximately 400 times the adrenal suppressive activity of cortisol when given subcutaneously to female rats. In adrenalectomized mice, fluocinonide has approximately 100 times the activity of cortisol with regard to the effect on the white blood count and depletion of eosinophils.

The sodium and potassium retaining activity of fluocinonide using desoxycorticosterone as a positive control was determined by subcutaneous injection in adrenalectomized male rats with a

dosage range of 1 to 16 mcg/rat. When no sodium load is given, there was a significant ($P<0.01$) increase in potassium excretion with the 16 mcg dose only. Significant ($P<0.05$) increase in potassium excretion was observed at all doses studied. When fluocinonide is given along with a sodium load, it produces only a slight elevation of urinary sodium, whereas a dose as low as 1 mcg/kg significantly ($P<0.01$) increases potassium excretion.

Vasoconstrictor Tests

Vasoconstrictor assay has proved to be a reliable human bioassay for the screening of compounds with topical corticosteroid activity, and for the comparative evaluation of biologic effects relative to existing standards.

Although the results of this standardized assay method cannot be directly equated with topical efficacy in dermatologic therapy, they appear to have definite predictive value, and to correlate well with clinical activity and potency. According to McKenzie, "the most powerful vasoconstrictors are those substances which clinical studies have shown to be the most effective topical anti-inflammatory agents". Vasoconstrictor tests were performed comparing fluocinonide creams and ointments to betamethasone 17-valerate, and hydrocortisone. Results of the alcoholic vasoconstrictor assay, demonstrate the relative activity of fluocinonide to be of the order of 400 times the activity of hydrocortisone and 4 times the activity of betamethasone 17-valerate.

Stoughton reports fluocinonide to be five times as potent as betamethasone 17-valerate in inducing vasoconstriction. The in vitro penetration* of fluocinonide and betamethasone is shown in the following table:

	Human* Skin	Hairless* Mouse Skin
Betamethasone 17-valerate	1.7	2.1
Fluocinonide	9.1	13.0

*Agent showing least in vitro penetration (fluocinolone alcohol) and least activity in vasoconstrictor bioassay (betamethasone alcohol and fluocinolone alcohol) listed as one (1.0). All other agents listed in the numerical ratio of their abilities to penetrate skin in vitro or induce vasoconstriction, respectively.

These data demonstrate that fluocinonide penetrates both human skin and hairless mouse skin better than betamethasone 17-valerate in this test system.

Place, V.A. et al., with a recent modification of the Stoughton-McKenzie Assay, demonstrated fluocinonide to have approximately five times the potency of betamethasone 17-valerate as determined by vasoconstriction in normal skin.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. They are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

The vasoconstrictor potency of fluocinonide gel 0.05% was compared, double-blind, to fluocinonide cream 0.05% and fluocinonide ointment 0.05% in 20 normal adult male and female volunteers. By this assay method, the fluocinonide gel 0.05% is at least as potent as the fluocinonide cream and ointment.

Absorption studies utilizing fluocinonide cream and ointment 0.05% in quantities of 30 to 60g/day (15 to 30 mg/day of active material) were done in 13 patients during 10 days. Transient suppression of adrenal activity has been noted in 3 out of 4 patients receiving 30 g/day of the cream under occlusion and in 2 out of 6 patients without occlusion. Transient adrenal suppression was noted with the application of 60 g/day of the cream in 2 patients out of 3 without occlusive therapy. Adrenal suppression can be expected in a number of patients with such large quantities since it is known that it depends on several factors such as the percentage of body surface treated, the concentration of the corticosteroid in the topical preparation, and most important, the integrity of the skin barrier. The adrenals apparently revert to normal function within 48 hours after cessation of therapy.

A similar study was done on 3 patients with a 0.01% solution of fluocinonide in propylene glycol using 15 ml/day. No adrenal suppression was observed.

Laboratory results for fasting blood sugar, SGPT or SGOT, blood urea nitrogen, serum potassium and serum sodium were determined in the patients entered in the above absorption studies. Examination of the data shows values to be in normal range.

A Draize test was performed on 213 healthy adult volunteers, one of whom had previous exposure to fluocinonide, the cream base or the ointment. There was no evidence of contact hypersensitivity to the cream or ointment formulation. However, in a few volunteers, a slight degree of erythema was noted which rapidly disappeared after removing the patch and it represented a very mild degree of irritation.

14 NON-CLINICAL TOXICOLOGY

Fluocinonide is an active synthetic corticosteroid. As judged by animal tests, the compound can be absorbed through the skin to produce systemic effects similar to those observed following oral, parenteral or aerosol administration.

In some cases, the LD_{50} of fluocinonide, when administered as a single intraperitoneal dose to rats, is of the same order of magnitude as that seen with other synthetic corticosteroids. In other cases, the LD_{50} value of this compound is lower. As with previously studied corticoids, the toxic effects include reduction in adrenal weight, liver changes, lung consolidation, septicemia, and gastrointestinal effects.

When deaths occurred, time after dosing with fluocinonide was about the same as that reported for other corticosteroids.

Subacute and chronic administration of fluocinonide to various species of laboratory animals produced typical corticosteroid effects, which included hyperglycemia, lymphopenia and changes in liver structure. These effects were generally not severe and were reversible with cessation of treatment.

No cleft palates or other skeletal anomalies were observed in pups from rabbits dosed with the compound during organogenesis.

15 SUPPORTING PRODUCT MONOGRAPHS

1. March C. et al. 1965) Adrenal function after topical steroid therapy. Clin Pharmaco Therap 6:43-9.

2. McKenzie AW. (1962) Percutaneous absorption of steroids. Arcj Derm 6:611-14.

3. McKenzie AW, Stoughton RB. (1962) Method for comparing percutaneous absorption of steroids. Arch derm 86: 608-10.

4. Place VA, et al. (1970) Precise evaluation of topically applied corticosteroid potency. Arch Derm 101:531-37.

5. Scholtz J R, Nelson DH. (1965) Some quantitative factors in topical corticosteroid therapy. Clin Pharmacol Therap 6:498-509.

6. Scoggins RB and Kliman B. (1965) Percutaneous absorption of corticosteroids. New Eng J. Med 273:831-40.

7. Stoughton R. (1969) Vasoconstrictor activity and percutaneous absorption of glucocorticoids. Arch Derm 99:753-56.

8. LIDEX (Flucinonide) 0.05% w/w, Topical, , submission control 246065; Product Monograph, Bausch Health Canada Inc., March 25, 2021.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrLYDERM

Fluocinonide
Ointment, Gel and Cream USP
0.05% w/w

Read this carefully before you start taking **LYDERM** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LYDERM.**

What is LYDERM used for?
LYDERM is used to treat skin rashes that are inflamed, itchy, or caused by allergies caused by certain skin conditions.

How does LYDERM work?
LYDERM provide relief from inflammation and symptoms by blocking the body's inflammatory response.

What are the ingredients in LYDERM? Medicinal ingredients: Fluocinonide
Non-medicinal ingredients:

- **Ointment:** Glyceryl Monostearate, Propylene Carbonate, Propylene Glycol, White Petrolatum, and White Wax
- **Gel:** Carbomer, Edetate Disodium, Propylene Glycol, Propyl Gallate, Purified Water and Sodium Hydroxide (to adjust the pH)
- **Cream:** Citric Acid, Glycerin, 1, 2, 6-Hexanetriol, Polyethylene Glycol 3350, Polyethylene Glycol 8000, Propylene Glycol, and Stearyl Alcohol

LYDERM (Flucinonide) comes in the following dosage forms:

- Ointment 0.05% w/w
- Gel 0.05% w/w
- Cream 0.05% w/w

Do not use LYDERM if you:

- are allergic to fluocinonide or any of the other ingredients found in LYDERM (Flucinonide).
- have untreated bacterial, tubercular, fungal, or viral lesions of the skin. This includes herpes simplex, vaccinia, and chickenpox.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LYDERM. Talk about any health conditions or problems you may have, including if you:

- are pregnant or if you think you might be pregnant
- are breastfeeding or plan to breastfeed

- have other inflammatory skin diseases caused by poor circulation such as stasis dermatitis or chronic ulcers in the legs.
- have adrenal gland problems. LYDERM can affect how your adrenal glands work.
- have a condition for which you were previously or are currently taking other corticosteroid drugs. Use of more than one corticosteroid at the same time or close in time may increase your chance of developing adrenal gland problems.
- have eye problems, such as cataracts. Talk to your doctor if you notice any change to your eyes or eyesight. Cataracts have been reported in patients using topical corticosteroids. Do NOT use LYDERM in or near the eyes. Take care not to get LYDERM in your eyes. If you get LYDERM in your eye, flush it with cold water right away.
- have liver problems
- have a skin infection.

Other warnings you should know about:

- Covering the treated area can increase the amount of medicine absorbed through your skin. This may increase your chance of developing adrenal gland problems. You should not cover the treated skin area with a bandage or other covering unless your healthcare professional tells you to. Using LYDERM for long time, over large areas of skin or on broken skin can also increase the amount of medicine absorbed through your skin.
- Using LYDERM for a long time may cause thinning of the skin. If you notice your skin thinning, speak to your healthcare professional.
- If you have to use LYDERM for a long time, your doctor may stop your treatment for a short period. Your doctor may also treat only one area of your body at a time. Your doctor will tell you exactly how to use LYDERM. Your doctor will also tell you how long you should be using LYDERM for.
- You may develop contact dermatitis (allergic skin reaction) while using LYDERM . Tell your healthcare professional if your skin is not healing or worsens.
- During the use of LYDERM (, you may develop other infections, such as bacterial infections of the skin.

The safety and how well LYDERM (Flucinonide) works has not been determined in patients under the age of 18 years.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Tell your healthcare professional if you have used or are currently using any products or medication containing corticosteroids.

The following may interact with LYDERM (Flucinonide):

- There are no known interactions with LYDERM (Flucinonide).

How to take LYDERM (Flucinonide):

- Use this medicine exactly as directed by your healthcare professional.
- Check that the pharmacist has provided you LYDERM (Flucinonide) as prescribed by your

doctor.
- LYDERM (Flucinonide) is for external use only.
- Do not cover the area with dressings unless instructed to do so by your doctor.

Ointment: the ointment is suitable for dry, itchy or scaly skin
Gel: the gel is used for lesions of the scalp
Cream: the cream is recommended for moist, weeping lesions.

Usual Dose:
Apply a small amount of LYDERM (Flucinonide) to the affected skin area, two to four times a day. Your doctor will tell your exactly how many times a day you should be applying LYDERM (Flucinonide).

Overdose:

If you think you have taken too much LYDERM (Flucinonide), contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not use extra medicine to make up for the missed dose.

What are possible side effects from using LYDERM (Flucinonide)?
These are not all the possible side effects you may feel when taking LYDERM (Flucinonide). If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:
- red, sore, itchy, blisters or oozing
- itching of the skin
- redness, rash, tears or scrapes
- heat rash (miliaria)
- application site pain or burning/stinging sensation
- change in skin pigmentation
- maceration of the skin. In this condition, the skin may feel soft, wet or soggy to touch
- thick and leathery skin
- skin dryness and flaking
- spider veins (telangiectasia)
- excessive hair growth over the body (hypertrichosis)
- tingling or prickling skin sensation
- inflamed hair follicles (folliculitis)
- acneiform eruptions, a type of acne
- striae (stretch marks that are red, pink or purple)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Skin atrophy: thinning of the skin		X	
Skin Irritation at the application site: red, sore or peeling skin; burning/stinging sensation; severe itching and/or dryness	X		
Dermatitis: skin rash or sores	X		
COMMON			
Allergic reactions: rash, hives, swelling of the skin			X
Cushing's syndrome (when your body makes too much cortisol hormone): rounded "moon" face, weight gain, pink or purple stretch marks (striae) on the skin, fragile skin that bruises easily, slow healing of cuts, severe fatigue, muscle weakness, headache			X
Glucocorticosteroid insufficiency (low levels of cortisol hormone): Worsening fatigue and muscle weakness, loss of appetite, weight loss, nausea, vomiting, and diarrhea			X

Glucosuria (excretion of glucose into the urine): feel extremely thirsty or dehydrated feel extremely hungry urinate more than usual urinate accidentally, unexplained weight loss fatigue trouble seeing slow-healing cuts, sores, or other injuries skin darkening in the folds of your neck, armpits, or other areas			X
Hyperglycemia (high levels of sugar): frequent urination, increased thirst, blurred vision, fatigue, headache, fruity-smelling breath, nausea and vomiting, shortness of breath, dry mouth, weakness, confusion, coma and abdominal pain			X
UNCOMMON			
Cataracts (clouding of the lens of the eye): clouded or blurred vision, double vision, difficulty in seeing during the night, sensitivity to light and glare, need for brighter than normal, light to read or see objects, seeing halo around lights, seeing objects in faded or yellow color, eye pain, headache due to changes in vision			X
Erythema: redness of the skin or mucous membrane			X
Gastroenteritis (stomach flu): diarrhea, vomiting stomach pain, cramping, fever, nausea, and headaches			X
Glaucoma (increased pressure in eye): loss of peripheral or side vision, seeing halos around lights, vision loss, redness in the eye, eye that looks hazy, eye pain, narrowed vision			X

Hypertension (high blood pressure)			X
Leukoderma: white patches on the skin			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Ointment, Gel and Cream**: Store at room temperature 15°C - 30°C.

Keep out of sight and reach of children.

If you want more information about LYDERM (Flucinonide):

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drugproduct-database.html); the manufacturer's website www.taro.com or by calling 1-800-361-4261.

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