

**PRODUCT MONOGRAPH  
INCLUDING PATIENT MEDICATION INFORMATION**

**PrLIDEMOL®**  
Fluocinonide Cream USP  
0.05% w/w

**Topical Corticosteroid**

**Bausch Health, Canada Inc.**  
2150 St-Elzear Blvd. West  
Laval, Quebec  
H7L 4A8

**Date of Revision:**  
March 19, 2021

Control #: 245941

LIDEMOL® is a trademark of Bausch Health Companies or its affiliates.

# TABLE OF CONTENTS

<b>TABLE OF CONTENTS .....</b>	<b>2</b>
<b>PART I: HEALTH PROFESSIONAL INFORMATION.....</b>	<b>4</b>
<b>1 INDICATIONS .....</b>	<b>4</b>
<b>2 CONTRAINDICATIONS .....</b>	<b>4</b>
<b>3 DOSAGE AND ADMINISTRATION .....</b>	<b>4</b>
3.1 Recommended Dose and Dosage Adjustment.....	4
<b>4 OVERDOSAGE .....</b>	<b>4</b>
<b>5 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.....</b>	<b>5</b>
<b>6 WARNINGS AND PRECAUTIONS .....</b>	<b>5</b>
6.1 General.....	5
6.2 Endocrine and Metabolism .....	5
6.3 Ophthalmic.....	6
6.4 Hepatic .....	6
6.5 Immune .....	6
6.6 Infections.....	6
6.7 Skin .....	6
6.8 Special Populations .....	7
6.8.1 Pregnancy and Lactation .....	7
6.8.2 Pediatrics .....	7
6.8.3 Geriatrics .....	7
6.9 Laboratory Tests .....	7
<b>7 ADVERSE REACTIONS.....</b>	<b>8</b>
7.1 Adverse Reaction Overview .....	8
7.2 Post-Market Adverse Reactions.....	8
<b>8 DRUG INTERACTIONS.....</b>	<b>8</b>
8.1 Overview.....	8
<b>9 ACTION AND CLINICAL PHARMACOLOGY .....</b>	<b>9</b>
9.1 Mechanism of Action.....	9
<b>10 STORAGE, STABILITY AND DISPOSAL .....</b>	<b>9</b>
<b>PART II: SCIENTIFIC INFORMATION.....</b>	<b>10</b>
<b>11 PHARMACEUTICAL INFORMATION.....</b>	<b>10</b>
<b>12 CLINICAL TRIALS.....</b>	<b>11</b>
12.1 Study Results.....	11
<b>13 DETAILED PHARMACOLOGY.....</b>	<b>11</b>

<b>14</b>	<b>NON-CLINICAL TOXICOLOGY .....</b>	<b>13</b>
<b>15</b>	<b>SUPPORTING PRODUCT MONOGRAPHS.....</b>	<b>14</b>
	<b>PATIENT MEDICATION INFORMATION .....</b>	<b>15</b>

## **PART I: HEALTH PROFESSIONAL INFORMATION**

### **1 INDICATIONS**

LIDEMOL (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**

LIDEMOL (fluocinonide) is suitable when an emollient effect is desired.

A small amount of LIDEMOL cream 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 LIDEMOL cream 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.**

<b>Route of Administration</b>	<b>Dosage Form / Strength/Composition</b>	<b>Non-medicinal Ingredients</b>
Topical	Cream 0.05 % w/w	Cetyl Alcohol, Citric Acid, Mineral Oil, Polysorbate 60, Propylene Glycol, Sorbitan Monostearate and Stearyl Alcohol.

LIDEMOL (0.05% w/w) cream contain fluocinonide in a water washable aqueous cream base. These formulations do not contain lanolin, parabens or phenolic compounds.

LIDEMOL (fluocinonide) cream, 0.05% w/w is available in 30g collapsible tubes and in 100g plastic jars.

## 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 reevaluated.

### 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 LIDEMOL 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, LIDEMOL 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 LIDEMOL 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 LIDEMOL 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 LIDEMOL 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 LIDEMOL.

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

Advise breastfeeding women not to apply LIDEMOL 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 LIDEMOL 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  $\geq 65$  years have been treated with LIDEMOL 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 steroids: 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, have 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 LIDEMOL 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 LIDEMOL.

## **9 ACTION AND CLINICAL PHARMACOLOGY**

### **9.1 Mechanism of Action**

LIDEMOL (fluocinonide) possess anti-inflammatory, anti-pruritic and vasoconstrictor actions.

## **10 STORAGE, STABILITY AND DISPOSAL**

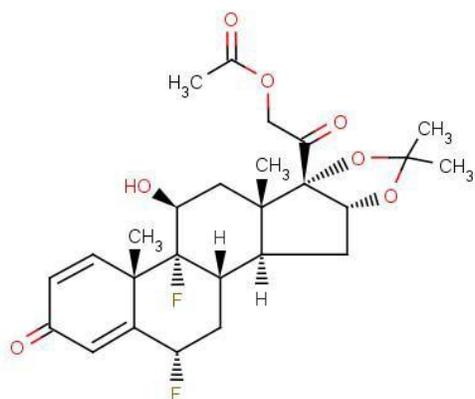
Store at room temperature, 15°C - 30°C.

## PART II: SCIENTIFIC INFORMATION

### 11 PHARMACEUTICAL INFORMATION

#### Drug Substance

Proper name:	Fluocinonide
Chemical name:	6 $\alpha$ , 9-difluoro-11 $\beta$ , 16 $\alpha$ , 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione, cyclic 16, 17-acetonide-21 acetate.
Molecular formula:	C <sub>26</sub> H <sub>32</sub> O <sub>7</sub> F <sub>2</sub>
Molecular mass:	494.52 g/mol
Structural formula:	



#### Physicochemical properties

Description:	Fluocinonide is a white to creamy white, 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

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.

## 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.

Absorption studies utilizing fluocinonide cream and ointment 0.05% w/w 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, none 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<sub>50</sub> 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<sub>50</sub> 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 Pharmacol Therap 6:43-9.
2. McKenzie AW. (1962) Percutaneous absorption of steroids. Arch Derm 86:611-14.
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 RBand 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.

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

**PrLIDEMOL®**  
Fluocinonide Cream USP

Read this carefully before you start taking **LIDEMOL** 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 **LIDEMOL**.

**What is LIDEMOL used for?**

LIDEMOL is used to treat skin rashes that are inflamed, itchy, or caused by allergies.

**How does LIDEMOL work?**

LIDEMOL provides relief from inflammation and symptoms by blocking the body's inflammatory response.

**What are the ingredients in LIDEMOL?**

Medicinal ingredients: Fluocinonide

Non-medicinal ingredients: Cetyl Alcohol, Citric Acid, Mineral Oil, Polysorbate 60, Propylene Glycol, Sorbitan Monostearate and Stearyl Alcohol.

**LIDEMOL comes in the following dosage forms:**

Cream, 0.05% w/w

**Do not use LIDEMOL if you:**

- are allergic to fluocinonide or any of the other ingredients found in LIDEMOL.
- have sores, cuts or wounds on your skin from bacteria, fungus, viruses or tuberculosis that have not been treated, such as:
  - herpes simplex,
  - vaccinia,
  - chickenpox.

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

- have a skin condition related to poor blood flow.
- have stasis dermatitis. This is a condition that affects the skin of the lower legs.
- have liver problems.
- have a condition for which you were previously or are now taking other corticosteroid drugs.
- have eye problems, such as cataracts.

**Other warnings you should know about:**

- LIDEMOL should not be used in the eye. Be careful when applying LIDEMOL on affected skin that is close to your eye. If LIDEMOL gets into your eye, it can cause irritation. Flush it with lots of water.
- Treatment with LIDEMOL can cause serious side effects including:
  - adrenal gland problems (called **adrenal insufficiency**).
  - **infections**. If this happens, you may be treated with other medications.
  - **Skin atrophy**, which is also known as thinning of the skin. If you notice that your skin is thinning, contact your healthcare professional. You may need to stop using LIDEMOL.
  - eye problems such as **cataracts** and **glaucoma**. Tell your healthcare professional if you notice any changes in your vision.

Some side effects are more common in children who are treated medications like LIDEMOL.

These side effects include:

- Adrenal gland problems
- Cushing's syndrome. This condition happens when there are higher than normal levels of cortisol in the blood.
- Stretch marks
- Delayed growth and weight gain
- Intracranial hypertension.

See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

- Higher levels of LIDEMOL can be absorbed through your skin in certain situations. This can increase your risk for adrenal gland problems. To lower your risk for these side effects:
  - Avoid covering the treated area with a bandage or other covering unless your healthcare professional tells you to.
  - Avoid using LIDEMOL for a long time and on large areas of skin or on cuts. If you will be using LIDEMOL for a long time, your healthcare professional may tell you to take breaks from time to time. They may also tell you to use it in on one part of the body at a time.
- Tell your healthcare professional if your skin is not healing or gets worse.
- **Testing:** Your healthcare professional may check your blood and urine during your treatment. This will tell them if LIDEMOL is affecting your adrenal glands.

**Female patients – Pregnancy and breastfeeding:**

- It is not known if using LIDEMOL while pregnant is safe for an unborn baby. Tell your healthcare professional if you are pregnant, think you are pregnant or get pregnant while using LIDEMOL.
- It is not known if LIDEMOL passes into breastmilk. Tell your healthcare professional if you are or will be breastfeeding a baby.

- If you are breastfeeding, avoid applying LIDEMOL to your nipple and areola. This will help to prevent the baby from getting LIDEMOL in their mouth.

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

**The following may interact with LIDEMOL:**

- There are no known interactions with LIDEMOL.

**How to take LIDEMOL:**

- Use exactly as directed by your healthcare professional. Your healthcare professional will tell you where to apply LIDEMOL.
- Be cautious when applying LIDEMOL on areas near the eye. Do not apply to the eyes. If LIDEMOL gets into your eye, flush it with lots of water.
- Gently apply a small amount onto the affected area 2 to 4 times per day.
- Do not cover the area with dressings unless you are told to do so by your healthcare professional.

**Usual dose:**

Gently apply a small amount of LIDEMOL to affected areas 2 to 4 times per day.

To reduce your risk for side effects, your healthcare professional may interrupt your dose. They may also tell you to treat one area of your body at a time.

**Overdose:**

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

**Missed dose:**

If you miss a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your usual schedule. Do not use extra medicine to make up for the missed dose.

**What are possible side effects from using LIDEMOL?**

These are not all the possible side effects you may feel when taking LIDEMOL. If you experience any side effects not listed here, contact your healthcare professional.

Skin problems including:

- red, sore, itchy, or oozing blisters
- itching
- burning
- scarring
- inflamed hair follicles
- stretch marks

- rash on skin around the mouth
- light coloured, wrinkly skin that may feel wet or soggy
- acne-like rash
- heat rash
- change in skin colour
- dryness and flaking
- spider veins
- excessive hair growth over the body
- infection
- tingling or prickling skin sensation
- redness, rash, tears or scrapes
- thick and leathery skin

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>Dermatitis:</b> skin rash or sores	X		
<b>Skin atrophy</b> (thinning of the skin): skin that tears or bruises easily, may be able to see blood vessels through the skin.		X	
<b>Skin irritation at the application site:</b> red, sore, or peeling skin; burning or stinging sensation; severe itching and / or dryness	X		
<b>COMMON</b>			
<b>Allergic reactions:</b> rash, hives, swelling of the skin			X
<b>Adrenal insufficiency</b> (when the adrenal glands don't make enough of the hormone cortisol): worsening fatigue and muscle weakness, loss of appetite, weight loss, nausea, vomiting, and diarrhea			X

<p><b>Cushing's syndrome</b> (when the body makes too much of the hormone cortisol): rounded “moon” face, weight gain, pink or purple stretch marks on the skin, fragile skin that bruises easily, slow healing of cuts, severe fatigue, muscle weakness, headache</p>			<p>X</p>
<p><b>Glucosuria</b> (sugar in 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</p>			<p>X</p>
<p><b>Hyperglycemia</b> (high blood sugar levels): 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</p>			<p>X</p>
<p><b>Second skin infection</b> (occurs during or following another infection): pus (a white, thick fluid composed of white blood cells), blisters, skin that becomes discoloured and painful</p>			<p>X</p>

UNCOMMON			
<b>Cataracts</b> (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
<b>Delayed growth and weight gain (in children):</b> poor or abnormally slow height and weight gain.			X
<b>Erythema:</b> redness of the skin or mucous membrane			X
<b>Gastroenteritis</b> (stomach flu): diarrhea, vomiting stomach pain, cramping, fever, nausea, and headaches			X
<b>Glaucoma</b> (increased pressure in eye): loss of side vision, seeing halos around lights, vision loss, redness in the eye, eye that looks hazy, eye pain, narrowed vision			X
<b>Hypertension</b> (high blood pressure): headache, dizziness, fatigue, difficulty breathing, chest pain, irregular heartbeat, nosebleed, nausea, vomiting. Sometimes there are no symptoms			X

<b>Intracranial hypertension in children</b> (increased pressure inside the skull): headache behind the eyes, ringing in the ears, blurred vision, double vision, short temporary episodes of blindness, nausea and vomiting, dizziness			X
<b>Leukoderma:</b> white patches on the skin			X
<b>Pustular form of psoriasis:</b> clearly defined, raised bumps that are filled with pus (a white, thick fluid composed of white blood cells)			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:**

Store at 15°C - 30°C.

Keep out of sight and reach of children.

**If you want more information about LIDEMOL:**

- 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.bauschhealth.ca](http://www.bauschhealth.ca), or by calling 1-800-361-4261.

This leaflet was prepared by:

**Bausch Health, Canada Inc.**

2150 St-Elzear Blvd., West

Laval, QC, H7L 4A8

[www.bauschhealth.ca](http://www.bauschhealth.ca)

Last Revised: March 19, 2021