

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-535

APPROVED LABELING

Draft Physician Package Insert

Clobex (clobetasol propionate) Lotion, 0.05%

Rx only

For dermatologic use only

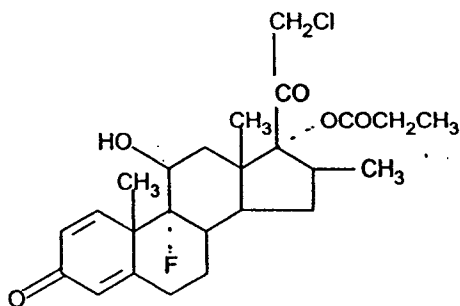
Not for ophthalmic, oral or intravaginal use

DESCRIPTION

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

Clobetasol propionate is 21-chloro-9-fluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17-propionate, with the empirical formula $C_{25}H_{32}ClFO_5$, a molecular weight of 466.98 (CAS Registry Number 25122-46-7).

The following is the chemical structure:



Clobetasol propionate

Clobetasol propionate is a white to practically-white crystalline powder insoluble in water.

Each gram of Clobex (clobetasol propionate) Lotion, 0.05% contains 0.5 mg of clobetasol propionate, in a vehicle base composed of hydroxypropyl methylcellulose, propylene glycol,

mineral oil, polyoxyethylene glycol 300 isostearate, carbomer, sodium hydroxide and purified water.

CLINICAL PHARMACOLOGY

Like other topical corticosteroids, Clobex (clobetasol propionate) Lotion, 0.05% has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids in general is unclear. However, corticosteroids are thought to act by induction of phospholipase A₂ inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A₂.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier and occlusion. For example, occlusive dressing with hydrocortisone for up to 24 hours has 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 other disease processes in the skin may increase percutaneous absorption.

There are no human data regarding the distribution of corticosteroids to body organs following topical application. Nevertheless, once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Due to the fact that circulating levels are usually below the level of detection, the use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary. They are metabolized, primarily in the liver, and are then excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

Clobex (clobetasol propionate) Lotion, 0.05% is in the super-high range of potency as compared with other topical corticosteroids in vasoconstrictor studies.

In studies evaluating the potential for hypothalamic-pituitary-adrenal (HPA) axis suppression, Clobex Lotion, 0.05% demonstrated rates of suppression that were numerically higher than those of a clobetasol propionate 0.05% cream (Temovate E® Emollient, 0.05%), (See PRECAUTIONS).

CLINICAL STUDIES

The efficacy of Clobex (clobetasol propionate) Lotion, 0.05% in psoriasis and atopic dermatitis has been demonstrated in two adequate and well-controlled clinical trials. The first study was conducted in patients with moderate to severe plaque psoriasis. Patients were treated twice daily for 4 weeks with either Clobex (clobetasol propionate) Lotion, 0.05% or vehicle lotion. Study results demonstrated that the efficacy of Clobex Lotion, 0.05% in treating moderate to severe plaque psoriasis was superior to that of vehicle.

At the end of treatment (4 weeks), 30 of 82 patients (36.6%) treated with Clobex Lotion, 0.05% compared with 0 of 29 (0%) treated with vehicle achieved success. Success was defined as a score of none or very mild (no or very slight clinical signs or symptoms of erythema, plaque elevation, or scaling) on the Global Severity scale of psoriasis.

The second study was conducted in patients with moderate to severe atopic dermatitis. Patients were treated twice daily for 2 weeks with either Clobex (clobetasol propionate) Lotion, 0.05% or vehicle lotion. Study results demonstrated that the efficacy of Clobex Lotion, 0.05% in treating moderate to severe atopic dermatitis was superior to that of vehicle.

At the end of treatment (2 weeks), 41 of 96 of patients (42.7%) treated with Clobex Lotion, 0.05% compared with 4 of 33 (12.1%) treated with vehicle achieved success. Success was defined as a score of none or very mild (no or very slight clinical signs or symptoms of

erythema, induration/papulation, oozing/crusting, or pruritus) on the Global Severity scale of atopic dermatitis.

INDICATIONS AND USAGE

Clobex (clobetasol propionate) Lotion, 0.05% is a super-high potent 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 (see PRECAUTIONS). Treatment should be limited to 2 consecutive weeks. The total dosage should not exceed 50 g (50 mL or 1.75 fl. oz.) per week.

For the treatment of moderate to severe plaque psoriasis, localized lesions (less than 10% body surface area) that have not sufficiently improved after the initial 2-week treatment with Clobex (clobetasol propionate) Lotion, 0.05% may be treated for up to 2 additional weeks. Any additional benefits of extending treatment should be weighed against the risk of HPA axis suppression before prescribing for more than 2 weeks.

Patients should be instructed to use Clobex (clobetasol propionate) Lotion, 0.05% for the minimum amount of time necessary to achieve the desired results (see PRECAUTIONS).

Use in patients younger than 18 years of age is not recommended due to numerically high rates of HPA axis suppression (see PRECAUTIONS: Pediatric Use).

CONTRAINDICATIONS

Clobex (clobetasol propionate) Lotion, 0.05% is contraindicated in patients who are hypersensitive to clobetasol propionate, to other corticosteroids, or to any ingredient in this preparation.

PRECAUTIONS

General: Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at the lowest doses tested.

Systemic absorption of topical corticosteroids has caused reversible adrenal suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which increase systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of adrenal suppression (see laboratory tests below). If adrenal suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

The effect of Clobex Lotion, 0.05% on HPA axis function was compared to clobetasol propionate cream 0.05% (Temovate E® Emollient, 0.05%) in adults in two studies, one for psoriasis and one for atopic dermatitis. In total, 8 of 10 evaluable patients with moderate to severe plaque psoriasis experienced adrenal suppression following 4 weeks of Clobex Lotion, 0.05% therapy (treatment beyond 4 consecutive weeks is not recommended in moderate to severe plaque psoriasis). In follow-up testing, 1 of 2 patients remained suppressed after 8 days. In this comparative study, for clobetasol propionate cream, 0.05% there were 3 of 10 evaluable patients with HPA axis suppression. Furthermore, 5 of 9 evaluable patients with moderate to severe atopic dermatitis experienced adrenal suppression following 2 weeks of Clobex Lotion, 0.05% therapy (treatment beyond 2 consecutive weeks is not recommended in

moderate to severe atopic dermatitis). Of the 3 patients that had follow-up testing, one patient failed to recover adrenal function 7 days post-treatment. For patients treated with clobetasol propionate cream, 0.05%, 4 of 9 evaluable patients experienced adrenal suppression following 2 weeks of treatment. Of the 2 patients that had follow-up testing, both recovered adrenal function 7 days post-treatment. The proportion of subjects suppressed may be underestimated because the adrenal glands were stimulated weekly with cosyntropin in these studies.

The potential increase in systemic exposure does not correlate with any proven benefit, but may lead to an increased potential for hypothalamic-pituitary-adrenal (HPA) axis suppression. Patients with acute illness or injury may have increased morbidity and mortality with intermittent HPA axis suppression. Patients should be instructed to use Clobex Lotion, 0.05% for the minimum amount of time necessary to achieve the desired results (See INDICATIONS AND USAGE).

If irritation develops, Clobex Lotion, 0.05% should be discontinued and appropriate alternative therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation, as with most topical products not containing corticosteroids.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, use of Clobex Lotion, 0.05% should be discontinued until the infection has been adequately controlled.

Clobex Lotion, 0.05% should not be used in the treatment of rosacea or perioral dermatitis, and should not be used on the face, groin, or axillae.

Information for Patients

Patients using topical corticosteroids should receive the following information and instructions:

- This medication is to be used as directed by the physician and should not be used longer than the prescribed time period.
- This medication should not be used for any disorder other than that for which it was prescribed.
- The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.
- Patients should wash their hands after applying the medication.
- Patients should report any signs of local or systemic adverse reactions to the physician.
- Patients should inform their physicians that they are using Clobex (clobetasol propionate) Lotion, 0.05% if surgery is contemplated.
- This medication is for external use only. It should not be used on the face, underarms or groin area, and avoid contact with the eyes and lips.
- As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, contact the physician.
- Patients should be informed to not use more than 50 g (50 mL or 1.75 fl. oz.) per week of Clobex Lotion, 0.05%.

Laboratory Tests

The following tests may be helpful in evaluating patients for HPA axis suppression:

- Cosyntropin stimulation test
- AM plasma cortisol test
- Urinary free cortisol test

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.

Clobetasol propionate was non-mutagenic in three different test systems: the Ames test, the *Saccharomyces cerevisiae* gene conversion assay, and the *E. coli* B WP2 fluctuation test.

Studies in the rat following subcutaneous administration at dosage levels up to 50 µg/kg per day revealed that the females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

Pregnancy: 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 to laboratory animals.

Clobetasol propionate is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent.

Teratogenicity studies in mice using the subcutaneous route resulted in fetotoxicity at the highest dose tested (1 mg/kg) and teratogenicity at all dose levels tested down to 0.03 mg/kg. These doses are approximately 1.4 and 0.04 times, respectively, the human topical dose of Clobex (clobetasol propionate) Lotion, 0.05%. Abnormalities seen included cleft palate and skeletal abnormalities.

In rabbits, clobetasol propionate was teratogenic at doses of 3 and 10 µg/kg. These doses are approximately 0.02 and 0.05 times, respectively, the human topical dose of Clobex (clobetasol propionate) Lotion, 0.05%. Abnormalities seen included cleft palate, cranioschisis, and other skeletal abnormalities.

A teratogenicity study in rats using the dermal route resulted in dose related maternal toxicity and fetal effects from 0.05 to 0.5 mg/kg/day of clobetasol propionate. These doses are approximately 0.14 to 1.4 times, respectively, the human topical dose of Clobex (clobetasol

propionate) Lotion, 0.05%. Abnormalities seen included low fetal weights, umbilical herniation, cleft palate, reduced skeletal ossification, and other skeletal abnormalities.

There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. Clobex (clobetasol propionate) Lotion, 0.05% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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 Clobex Lotion, 0.05% is administered to a nursing woman.

Pediatric Use

Use of Clobex Lotion, 0.05% in pediatric patients is not recommended due to the potential for HPA axis suppression (see PRECAUTIONS: General).

The HPA axis suppression potential of Clobex 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 patients were evaluated for HPA axis function. Patients were treated twice daily for 2 weeks with Clobex Lotion, 0.05%. After 2 weeks of treatment, 9 out of 14 of the patients experienced adrenal suppression. One out of 4 patients treated with Clobex Lotion, 0.05% who were retested remained suppressed two weeks post-treatment. In comparison, 2 of 10 of the patients treated with clobetasol propionate cream, 0.05% demonstrated HPA axis suppression. One patient who was retested recovered.

None of the patients 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 Clobex Lotion, 0.05%. However, patients with acute illness or injury may have increased morbidity and mortality with intermittent HPA axis suppression.

Because of a 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 Clobex (clobetasol propionate) Lotion, 0.05% did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients. 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.

ADVERSE REACTIONS

In controlled clinical trials with Clobex (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 Clobex (clobetasol propionate) Lotion, 0.05% at 1.0% or greater was:

<u>Adverse Reaction</u>	<u>Incidence</u>
Skin Atrophy	4.2 %
Telangiectasia	3.2 %
Discomfort Skin	1.3 %
Skin Dry	1.0 %

Other local adverse events occurred at rates less than 1.0%. Similar rates of local adverse reactions were reported in the comparator (clobetasol propionate cream, 0.05%). Most local adverse events were rated as mild to moderate and they are not affected by age, race or gender.

The following additional local adverse reactions have been reported with topical corticosteroids. They may occur more frequently with the use of occlusive dressings and higher potency corticosteroids including clobetasol propionate. These reactions are listed in an approximate decreasing order of occurrence: irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

OVERDOSAGE

Topically applied Clobex (clobetasol propionate) Lotion, 0.05% can be absorbed in sufficient amount to produce systemic effects (See PRECAUTIONS).

DOSAGE AND ADMINISTRATION

Clobex Lotion, 0.05% should be applied to the affected skin areas twice daily and rubbed in gently and completely. (See INDICATIONS AND USAGE.)

Clobex Lotion, 0.05% contains a super-high potent 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 very localized lesions of moderate to severe plaque psoriasis (no more than 10 % body surface area) that have not sufficiently improved after the initial 2 weeks of treatment with Clobex (clobetasol propionate) Lotion 0.05%.

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.

Therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Use in patients younger than 18 years is not recommended because of numerically high rates of HPA axis suppression (See PRECAUTIONS: Pediatric Use).

Unless directed by physician, Clobex Lotion, 0.05% should not be used with occlusive dressings.

HOW SUPPLIED

Clobex Lotion, 0.05% is supplied in the following sizes:

- 1 fl. oz. / 30 mL (NDC 0299-3848-01) high density polyethylene bottles.
- 2 fl. oz. / 59 mL (NDC 0299-3848-02) high density polyethylene bottles.
- 4 fl. oz. / 118 mL (NDC 0299-3848-04) high density polyethylene bottles.

Store at Controlled Room Temperature 68° – 77°F (20° – 25°C)

Protect from freezing.

Manufactured for:

GALDERMA Laboratories, L.P.
14501 North Freeway
Fort Worth, Texas 76177

By:

DPT Laboratories, Ltd.
307 E. Josephine Street
San Antonio, Texas 78215

GALDERMA is a registered trademark.

Revised: July 24, 2003.

PATIENT INFORMATION

Clobex™ (clobetasol propionate) Lotion, 0.05%

For External Use Only

Not for Ophthalmic (Eye) Use

Read the Patient Information that comes with Clobex™ (KLO-bex) Lotion before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is Clobex™ Lotion?

Clobex™ Lotion is a medicine called a topical (skin use only) corticosteroid. It is used for a short time to reduce the inflammation and itching of:

- Moderate to severe skin conditions (atopic dermatitis and other skin problems)
- Moderate to severe plaque psoriasis.

Clobex™ Lotion is a super-high potent (very strong) topical corticosteroid. It is very important that you use Clobex™ Lotion only as directed, in order to avoid serious side effects.

Who should not use Clobex™ Lotion?

Do not use Clobex™ Lotion if you are allergic to any of its ingredients, or to any other corticosteroid. The active ingredient is clobetasol propionate. See the end of this leaflet for the complete list of other ingredients in Clobex™ Lotion. Ask your doctor or pharmacist if you need a list of other corticosteroids.

Clobex™ Lotion is not recommended for use on anyone younger than 18 years of age. Clobex™ Lotion has not been studied in children under 12 years old. Children have smaller body sizes and have a higher chance of side effects.

What should I tell my doctor before using Clobex™ Lotion?

Tell your doctor:

- if you are pregnant, think you are pregnant, or plan to be pregnant. Talk with your doctor before using Clobex™ Lotion or if you are already using Clobex Lotion, as it is not known if Clobex™ Lotion can harm your unborn child.
- if you are breastfeeding. It is not known if Clobex™ Lotion passes into your milk.
- if you think you have a skin infection. You may need another medicine to treat the skin infection before you use Clobex™ Lotion.

Tell your doctor about all the other medicines and skin products you use, including prescription and non-prescription medicines, cosmetics, vitamins, and herbal supplements. Some medicines can cause serious side effects if used while you are using Clobex™ Lotion.

How should I use Clobex™ Lotion?

- Use Clobex™ Lotion exactly as directed by your doctor. Clobex™ Lotion is for skin use only.
- Apply Clobex™ Lotion twice a day, once in the morning and once at night, or as directed by your doctor. Use only enough to cover the affected areas. **Do not apply Clobex™ Lotion to your face, neck, groin or armpits. Do not get Clobex™ Lotion on your lips or in or near your eyes.**
- Make sure your skin is clean and dry before applying Clobex™ Lotion.
- Turn the bottle of Clobex™ Lotion upside down. Pour a small amount, less than 1 teaspoonful of Clobex™ Lotion onto your fingertips, or directly on your affected skin area. Gently, rub the Clobex™ Lotion into your affected skin area, until the lotion disappears.
- Wash your hands after using Clobex™ Lotion.
- If you forget to apply Clobex™ Lotion at the scheduled time, use it as soon as you remember. Then go back to your regular schedule. If it is about time for your next dose, apply just that 1 dose, and continue with your normal application schedule. Do not try to make up for the missed dose. If you miss several doses, tell your doctor.
- Throw away unused Clobex™ Lotion.

What should I avoid while using Clobex™ Lotion?

Do not do the following while using Clobex™ Lotion:

- **Do not get Clobex™ Lotion on your face, lips, or in or near your eyes** because this might cause irritation. If you do, use a lot of water to rinse the Clobex™ Lotion off your face, lips, or out of your eyes. If your eyes keep stinging after rinsing them well with water, call your doctor right away.
- **Do not apply Clobex™ Lotion to your groin or armpits.**
- **Do not bandage or cover your treated areas unless your doctor tells you to do so.**
- **Do not wear tight fitting clothes over your treated skin areas.**
- **Do not use Clobex™ Lotion any longer than 2 weeks (14 days) for moderate to severe conditions (atopic dermatitis and other skin problems).**
- **Do not use Clobex™ Lotion any longer than an extra 2 weeks (4 weeks total) for psoriasis on a small area of your body (less than 10 percent of your body surface area) that is not much better after the first 2 weeks of treatment.**
- **Do not use more than 50 grams (50 mL or 1.75 fluid ounces) of Clobex™ Lotion a week.** Clobex™ Lotion comes in 3 different size bottles, a 1-ounce, 2-ounce, and a 4-ounce bottle.

What are the possible side effects of Clobex™ Lotion?

Clobex™ Lotion can pass through your skin. Too much Clobex™ Lotion passing through your skin can shut down your adrenal glands. This usually happens if you use too much Clobex™ Lotion, or you use it for too long. If this happens, your adrenal glands may not start working immediately once you stop using Clobex™ Lotion. **Shutting down of the adrenal glands can cause nausea, vomiting, fever, low blood pressure, heart attack, and even death because your body cannot respond to any stress or illness.**

Your doctor may do special blood and urine tests to check your adrenal gland function while you are using Clobex™ Lotion.

Other possible side effects with Clobex™ Lotion include mild burning, stinging, itching, redness, irritation, and dry skin. Also, thinning of the skin, widening of small blood vessels in the skin, and skin discomfort at the site of application may happen. Sometimes your condition will get worse with use of Clobex™ Lotion.

If you are ill or injured, or going to have surgery, tell your doctor that you are using Clobex™ Lotion.

Tell your doctor if you:

- are going to have surgery.
- get sick or don't feel right. Call your doctor right away.
- have irritation of the treated skin area that does not go away.
- have any unusual effects that you do not understand.
- have affected areas that do not seem to be getting better after 2 weeks of using Clobex™ Lotion.

These are not all the possible side effects of Clobex™ Lotion. For more information, ask your doctor or pharmacist.

General information about the safe and effective use of Clobex™ Lotion.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Clobex™ Lotion for a condition for which it was not prescribed. Do not give Clobex™ Lotion to other people, even if they have the same symptoms you have. It may harm them. **Keep Clobex™ Lotion and all medicines out of reach of children.**

This leaflet summarizes the most important information about Clobex™ Lotion. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Clobex™ Lotion that is written for health professionals.

What are the ingredients of Clobex™ Lotion?

Active Ingredient: clobetasol propionate

Inactive Ingredients: hydroxypropyl methylcellulose, propylene glycol, mineral oil, polyoxyethylene glycol 300 isostearate, carbomer, sodium hydroxide and purified water.

Rx Only

Manufactured for:

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Fort Worth, Texas 76177

By:

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San Antonio, Texas 78215

GALDERMA is a registered trademark.

Revised: July 24, 2003

0.5 fl. oz. (15 mL) Physician sample (bottle/BOX) label¹

Principal display panel

NDC 0299-3848-05

Rx only

Clobex Lotion, 0.05%
(clobetasol propionate)

GALDERMA Logo

0.5 fl. oz. (15 mL)

SAMPLE, NOT FOR SALE

Information panel

For external use only. Not for eye use.

Usual dosage: see package insert for complete prescribing information.

Each gram contains: Active: clobetasol propionate 0.5 mg.
Inactive: hydroxypropylmethyl cellulose, polyoxyethylene glycol 300 isostearate, carbomer, mineral oil, propylene glycol, sodium hydroxide and purified water.

Store at Controlled Room Temperature 68° – 77°F (20° – 25°C)

Protect from freezing.

See lot No. and exp. date on bottom of bottle.

Distributed by:
GALDERMA Laboratories, L.P.
14501 North Freeway
Fort Worth, Texas 76177

Manufactured by:
DPT Laboratories, Ltd.
307 E. Josephine Street
San Antonio, Texas 78215

¹ Due to minimal space and type size limitations for printing small labels, the information for the sample size has been abbreviated within the limits established by 21 CFR 201.10(i).

1 fl. oz. (30 mL) Trade size (bottle/BOX) label

Principal display panel

NDC 0299-3848-01

Rx only

Clobex Lotion, 0.05%
(clobetasol propionate)

GALDERMA Logo

1 fl. oz. (30 mL)

Information panel

For external use only. Not for eye use.

Usual dosage: Apply twice daily, once in the morning and once at night. Use only enough to cover the affected areas. Do not apply Clobex Lotion, 0.05% to the face, underarms, or groin and avoid contact with eyes and lips. See package insert for complete prescribing information.

Each gram contains: Active: clobetasol propionate 0.5 mg.
Inactive: hydroxypropylmethyl cellulose, polyoxyethylene glycol 300 isostearate, carbomer, mineral oil, propylene glycol, sodium hydroxide and purified water.

Store at Controlled Room Temperature 68° – 77°F (20° – 25°C)

Protect from freezing.

See lot No. and exp. date on bottom of bottle.

Marketed by:
GALDERMA Laboratories, L.P.
14501 North Freeway
Fort Worth, Texas 76177

Manufactured by:
DPT Laboratories, Ltd.
307 E. Josephine Street
San Antonio, Texas 78215

2 fl. oz. (59 mL) Trade size (bottle/BOX) label

Principal display panel

NDC 0299-3848-02

Rx only

Clobex Lotion, 0.05%
(clobetasol propionate)

GALDERMA Logo

2 fl. oz. (59 mL)

Information panel

For external use only. Not for eye use.

Usual dosage: Apply twice daily, once in the morning and once at night. Use only enough to cover the affected areas. Do not apply Clobex Lotion, 0.05% to the face, underarms, or groin and avoid contact with eyes and lips. See package insert for complete prescribing information.

Each gram contains: Active: clobetasol propionate 0.5 mg.
Inactive: hydroxypropylmethyl cellulose, polyoxyethylene glycol 300 isostearate, carbomer, mineral oil, propylene glycol, sodium hydroxide and purified water.

Store at Controlled Room Temperature 68° – 77°F (20° – 25°C)

Protect from freezing.

See lot No. and exp. date on bottom of bottle.

Marketed by:
GALDERMA Laboratories, L.P.
14501 North Freeway
Fort Worth, Texas 76177

Manufactured by:
DPT Laboratories, Ltd.
307 E. Josephine Street
San Antonio, Texas 78215

4 fl. oz. (118 mL) Trade size (bottle/BOX) label

Principal display panel

NDC 0299-3848-04

Rx only

Clobex Lotion, 0.05%
(clobetasol propionate)

GALDERMA Logo

4 fl. oz. (118 mL)

Information panel

For external use only. Not for eye use.

Usual dosage: Apply twice daily, once in the morning and once at night. Use only enough to cover the affected areas. Do not apply Clobex Lotion, 0.05% to the face, underarms, or groin and avoid contact with eyes and lips. See package insert for complete prescribing information.

Each gram contains: Active: clobetasol propionate 0.5 mg.
Inactive: hydroxypropylmethyl cellulose, polyoxyethylene glycol 300 isostearate, carbomer, mineral oil, propylene glycol, sodium hydroxide and purified water.

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Protect from freezing.

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307 E. Josephine Street
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FILENAME	SO 1 Lett	SO 2 Lett	date Letter Rec	actions Com	actions Com	Letter to ML
21178N000,se5-007_Clinical_BPCA	BPCA	TAUB	1/16/2004		1/20/2004	1/20/2004
21178N000,se5-007_Pharma_BPCA	BPCA	MASON	1/23/2004	1/23/2004	1/23/2004	1/23/2004
21121se1-008_BPCA_pharm_biopharm	BPCA	CASTLE	2/13/2004	2/13/2004	2/13/2004	2/13/2004
19922seg-005_BPCA_Corlopam_clinical_review	BPCA	TAUB	2/25/2004	2/25/2004	3/4/2004	3/4/2004
21121se1-008_concerta_BPCA_clinical_Review	BPCA	CASTLE	3/5/2004	3/5/2004	3/5/2004	3/5/2004
20630se5-005_Ultiva_Pharm_Biopharm_BPCA	BPCA	TAUB	3/9/2004	3/9/2004	3/9/2004	3/9/2004
20905se5-012_Arava_Clinical_BPCA	BPCA	TAUB	3/9/2004	3/9/2004	3/9/2004	3/9/2004
001_bpca	BPCA	TAUB	3/18/2004	3/18/2004	3/18/2004	3/18/2004
001_bpca	BPCA	TAUB	3/22/2004	3/23/2004	3/23/2004	3/23/2004
21690_ortho_Pharm_biopharm	BPCA	TAUB	3/15/2004	3/16/2004	3/16/2004	3/16/2004
21690_ortho-tri-cyclen_bpca_clinical_BPCA	BPCA	TAUB	3/23/2004	3/24/2004	3/24/2004	3/24/2004
19537_Cipro_BPCA_Pharm_Biopharm	BPCA	TAUB	3/25/2004	3/26/2004	3/26/2004	3/26/2004
19537_Cipro_BPCA_clinical	BPCA	TAUB	3/25/2004	3/26/2004	3/26/2004	3/26/2004
19922_BPCA_Corlopam_Clinical_Review	BPCA	CASTLE	4/2/2004	4/2/2004	4/2/2004	4/2/2004
005_corlopam_BPCA_pharm_biopharm	BPCA	CASTLE	4/2/2004	4/2/2004	4/2/2004	4/2/2004
21228se8-006_detrol_bpca_clinical	BPCA	TAUB	4/9/2004	4/12/2004	4/12/2004	4/12/2004
21228se8-006_detrol_bpca_pharm_biopharm	BPCA	TAUB	4/9/2004	4/12/2004	4/12/2004	4/12/2004