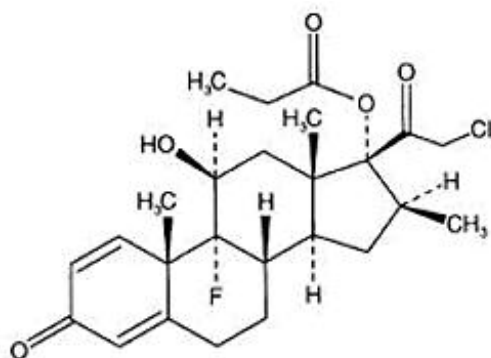


CLOBEX - clobetasol propionate spray
Physicians Total Care, Inc.

DESCRIPTION

CLOBEX[®] (clobetasol propionate) Spray, 0.05% contains clobetasol propionate, a synthetic fluorinated corticosteroid, for topical use. The corticosteroids constitute a class of primarily synthetic steroids used topically as anti-inflammatory and antipruritic agents. 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 C₂₅H₃₂ClFO₅, and a molecular weight of 466.97 (CAS Registry Number 25122-46-7).

The following is the chemical structure:



Clobetasol propionate

Clobetasol propionate is a white to almost white crystalline powder that is practically insoluble in water. Each gram of CLOBEX[®] (clobetasol propionate) Spray, 0.05% contains 0.5 mg of clobetasol propionate, in a vehicle base composed of alcohol, isopropyl myristate, sodium lauryl sulfate, and undecylenic acid.

CLINICAL PHARMACOLOGY

Like other topical corticosteroids CLOBEX[®] (clobetasol propionate) Spray, 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. 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 metabolic pathways similar to systemically administered corticosteroids. 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) Spray, 0.05% is in the super-high range of potency as compared with other topical corticosteroids in a vasoconstrictor study conducted in healthy subjects. However,

similar blanching scores do not necessarily imply therapeutic equivalence.

The effect of CLOBEX[®] (clobetasol propionate) Spray, 0.05% on hypothalamic-pituitary-adrenal (HPA) axis function was investigated in adults in two studies. In the first study, patients with plaque psoriasis covering at least 20% of their body applied CLOBEX[®] (clobetasol propionate) Spray, 0.05% twice daily for up to 4 weeks. Fifteen percent (2 out of 13) of patients displayed adrenal suppression after 4 weeks of use based on the Cosyntropin Stimulation Test. The laboratory suppression was transient; all subjects returned to normal after cessation of drug use. In the second study, patients with plaque psoriasis covering at least 20% of their body applied CLOBEX[®] (clobetasol propionate) Spray, 0.05% twice daily for either 2 or 4 weeks. Nineteen percent (4 out of 21) of patients treated for 2 weeks and 20% (3 out of 15) of patients treated for 4 weeks displayed adrenal suppression at the end of treatment based on the Cosyntropin Stimulation Test. The laboratory suppression was transient; all subjects returned to normal after cessation of drug use. In these studies, HPA axis suppression was defined as serum cortisol level ≤ 18 $\mu\text{g/dL}$ 30-min post cosyntropin (ACTH₁₋₂₄) stimulation (See **PRECAUTIONS**).

CLINICAL STUDIES

The efficacy of CLOBEX[®] (clobetasol propionate) Spray, 0.05% in psoriasis has been demonstrated in two randomized, vehicle controlled clinical trials, which were identical in design. The studies were conducted in patients aged 18 years and older with moderate to severe plaque psoriasis. Patients were treated twice daily for up to 4 weeks with either CLOBEX[®] (clobetasol propionate) Spray, 0.05% or vehicle spray.

Patients were evaluated on their Overall Disease Severity, a 5-point scale based on scaling, erythema, and plaque elevation that classified subjects as clear, almost clear, mild, moderate, or severe/very severe. Only patients classified as moderate or severe/very severe at baseline were enrolled in the studies. The median percent body surface area (BSA) at baseline was 6% for the two studies. The numbers of patients scored as clear or almost clear at Weeks 2 and 4 are presented in Table 1.

Table 1-Number of Patients Clear or Almost Clear on the Overall Disease Severity Scale at Weeks 2 and 4

		Study 1		Study 2	
		CLOBEX [®] N=60	Vehicle N=60	CLOBEX [®] N=60	Vehicle N=60
Week 2	Clear	1 (2%)	0 (0%)	0 (0%)	0 (0%)
	Almost Clear	32 (53%)	1 (2%)	28 (47%)	0 (0%)
Week 4	Clear	15 (25%)	0 (0%)	18 (30%)	0 (0%)
	Almost Clear	32 (53%)	2 (3%)	31 (52%)	1 (2%)

INDICATIONS AND USAGE

CLOBEX[®] (clobetasol propionate) Spray, 0.05% is a super-high potent topical corticosteroid formulation indicated for the treatment of moderate to severe plaque psoriasis affecting up to 20% body surface area (BSA) in patients 18 years of age or older (see **PRECAUTIONS**). Treatment should be

limited to 4 consecutive weeks. The total dosage should not exceed 50 g (59 mL or 2 fl. oz.) per week.

Before prescribing for more than 2 weeks, any additional benefits of extending treatment to 4 weeks should be weighed against the risk of HPA axis suppression.

Patients should be instructed to use CLOBEX[®] (clobetasol propionate) Spray, 0.05% for the minimum amount of time necessary to achieve the desired results (see **PRECAUTIONS**).

Use in patients under 18 years of age is not recommended because safety has not been established and because numerically high rates of HPA axis suppression were seen with other clobetasol propionate topical formulations (see **PRECAUTIONS: Pediatric Use**).

CONTRAINDICATIONS

CLOBEX[®] (clobetasol propionate) Spray, 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.

In studies evaluating the potential for hypothalamic-pituitary-adrenal (HPA) axis suppression, using the Cosyntropin Stimulation Test, CLOBEX[®] (clobetasol propionate) Spray, 0.05% demonstrated rates of suppression that were comparable after 2 and 4 weeks of twice-daily use (19% and 15-20%, respectively), in adult patients with moderate to severe plaque psoriasis ($\geq 20\%$ BSA). In these studies, HPA axis suppression was defined as serum cortisol level ≤ 18 $\mu\text{g/dL}$ 30-min post cosyntropin stimulation (See **CLINICAL PHARMACOLOGY**).

Patients with acute illness or injury may have increased morbidity and mortality with intermittent HPA axis suppression. Patients should be instructed to use CLOBEX[®] (clobetasol propionate) Spray, 0.05% for the minimum amount of time necessary to achieve the desired results (See **INDICATIONS AND USAGE**).

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.

HPA axis suppression has not been evaluated in psoriasis patients treated with CLOBEX[®] (clobetasol propionate) Spray, 0.05% who are less than 18 years old. Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios (see **PRECAUTIONS: Pediatric Use**). 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.

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.

If irritation develops, CLOBEX[®] (clobetasol propionate) Spray, 0.05% should be discontinued and

appropriate 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[®] (clobetasol propionate) Spray, 0.05% should be discontinued until the infection has been adequately controlled.

CLOBEX[®] (clobetasol propionate) Spray, 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) Spray, 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. Also 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.
- Do not exceed 30 sprays per application or 60 sprays per day.
- Patients should not use more than 50 g (59 mL or 2 fl.oz.) per week of CLOBEX[®] (clobetasol propionate) Spray, 0.05%.

Instructions to the Pharmacist:

1. Remove the spray pump from the wrapper
2. Remove and discard the cap from the bottle
3. Keeping the bottle vertical, insert the spray pump into the bottle and turn clockwise until well-fastened
4. Dispense the bottle with the spray pump inserted

Laboratory Tests

The cosyntropin stimulation test may be helpful in evaluating patients for HPA axis suppression. Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Clobetasol propionate was negative in the *in vitro* mammalian chromosomal aberration test and in the *in vivo* mammalian erythrocyte micronucleus test.

The effect of subcutaneously administered clobetasol propionate on fertility and general reproductive toxicity was studied in rats at doses of 0, 12.5, 25, and 50 µg/kg/day. Males were treated beginning 70 days before mating and females beginning 15 days before mating through day 7 of gestation. A dosage level of less than 12.5 µg/kg/day clobetasol propionate was considered to be the no-observed-effect-level (NOEL) for paternal and maternal general toxicity based on decreased weight gain and for male reproductive toxicity based on increased weights of the seminal vesicles with fluid. The female reproductive NOEL was 12.5 µg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m²/day basis) based on reduction in the numbers of estrous cycles during the pre-cohabitation

period and an increase in the number of nonviable embryos at higher doses.

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

The effect of clobetasol propionate on pregnancy outcome and development of offspring was studied in the rat.

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

There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. CLOBEX[®] (clobetasol propionate) Spray, 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[®] (clobetasol propionate) Spray, 0.05% is administered to a nursing woman.

Pediatric Use

Use in patients under 18 years of age is not recommended, because safety has not been established and because numerically high rates of HPA axis suppression were seen with other clobetasol propionate topical formulations. Safety and effectiveness in pediatric patients treated with CLOBEX[®] (clobetasol propionate) Spray, 0.05% have not been established (see **PRECAUTIONS: General**).

Because of higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of glucocorticosteroid insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids.

Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric Use

Clinical studies of CLOBEX[®] (clobetasol propionate) Spray, 0.05% did not include sufficient numbers of patients aged 65 and over to adequately determine whether they respond differently than younger patients. In the two Phase 3 studies, 21 of the 240 patients (9%) were over the age of 65. 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) Spray, 0.05%, the most common adverse reaction was burning at the site of application [40% of subjects treated with CLOBEX[®] (clobetasol propionate) Spray, 0.05% and 47% of subjects treated with Spray Vehicle]. Other commonly reported adverse reactions for CLOBEX[®] (clobetasol propionate) Spray, 0.05% and Spray Vehicle, respectively, are noted in Table 2.

Table 2 - Commonly Occurring Adverse Events

<u>Adverse Reaction</u>	Clobetasol Propionate 0.05% Spray (N=120)	Vehicle Spray (N=120)
System Organ Class		
General disorders and administration site conditions	50 (42%)	56 (47%)
Application site atrophy	0 (0%)	1 (1%)
Application site burning	48 (40%)	56 (47%)
Application site dryness	2 (2%)	0 (0%)
Application site irritation	1 (1%)	0 (0%)
Application site pain	1 (1%)	2 (2%)
Application site pigmentation changes	1 (1%)	0 (0%)
Application site pruritus	4 (3%)	3 (3%)
Infections and infestations	17 (14%)	12 (10%)
Influenza	0 (0%)	2 (2%)
Nasopharyngitis	6 (5%)	3 (3%)
Pharyngitis streptococcal	1 (1%)	0 (0%)
Upper respiratory tract infection	10 (8%)	2 (2%)
Skin and subcutaneous tissue disorders	4 (3%)	2 (2%)
Eczema asteatotic	2 (2%)	0 (0%)

Other adverse events occurred at rates less than 1.0%. 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: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

Systemic absorption of topical corticosteroids has produced hypothalamic-pituitary-adrenal (HPA) axis suppression manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

OVERDOSAGE

Topically applied CLOBEX[®] (clobetasol propionate) Spray, 0.05% can be absorbed in sufficient amount to produce systemic effects. (See **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION

CLOBEX[®] (clobetasol propionate) Spray, 0.05% should be sprayed directly onto the affected skin areas twice daily and rubbed in gently and completely. Do not exceed 30 sprays per application or 60 sprays per day. (See **INDICATIONS AND USAGE**).

CLOBEX[®] (clobetasol propionate) Spray, 0.05% contains a super-high potent topical corticosteroid; therefore treatment should be limited to 4 weeks. Treatment beyond 2 weeks should be limited to localized lesions of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment with CLOBEX[®] (clobetasol propionate) Spray, 0.05%.

The total dosage should not exceed 50 g (59 mL or 2 fluid ounces) 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 pediatric patients younger than 18 years is not recommended because of the potential for HPA axis suppression. (See **PRECAUTIONS: Pediatric Use**).

Unless directed by physician, CLOBEX[®] (clobetasol propionate) Spray, 0.05% should not be used with occlusive dressings.

HOW SUPPLIED

CLOBEX[®] (clobetasol propionate) Spray, 0.05% is supplied in a white HDPE bottle with a white polypropylene cap and white LDPE liner in the following size:

2 fl oz/59 mL **NDC 54868-5510-0**

Storage: Keep tightly closed. Store under controlled room temperature conditions 20°C - 25°C (68°F - 77°F) with excursions permitted between 15°C and 30°C (59°F and 86°F). Do not freeze, refrigerate or store above 30°C. Spray is flammable; keep away from heat or flame.

US Patent Nos: 5,972,920; 5,990,100 and foreign patents pending.

Marketed by:
GALDERMA LABORATORIES, L.P.
Fort Worth, Texas 76177 USA

Manufactured by:
CPL
Mississauga, Ontario, Canada L5N 6L6
Made in Canada.
GALDERMA is a registered trademark.
www.clobex.com
2004953-0409
Revised: April 2009

Relabeling of "Additional Barcode" label by:

Physicians Total Care, Inc.
Tulsa, OK 74146

PATIENT INFORMATION

CLOBEX[®] (clobetasol propionate) Spray, 0.05%

For External Use Only

Not for Ophthalmic (Eye) Use

Read the Patient Information that comes with CLOBEX[®] (KLO-bex) Spray 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[®] Spray?

CLOBEX[®] Spray 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 plaque psoriasis.

CLOBEX[®] Spray is a super-high potent (very strong) topical corticosteroid. It is very important that you use CLOBEX[®] Spray only as directed, in order to avoid serious side effects.

Who should not use CLOBEX[®] Spray?

Do not use CLOBEX[®] Spray 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[®] Spray.

CLOBEX[®] Spray is not recommended for use on anyone younger than 18 years of age because the adrenal glands may shut down. (see section on “**What are the possible side effects of CLOBEX[®] Spray?**”). Children have smaller body sizes and have a higher chance of side effects.

What should I tell my doctor before using CLOBEX[®] Spray?

Tell your doctor:

- if you are pregnant, think you are pregnant or plan to be pregnant. Talk with your doctor before using CLOBEX[®] Spray or if you are already using CLOBEX[®] Spray, as it is not known if CLOBEX[®] Spray can harm your unborn child.
- if you are breastfeeding. It is not known if CLOBEX[®] Spray 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[®] Spray.

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[®] Spray.

How should I use CLOBEX[®] Spray?

- Use CLOBEX[®] Spray exactly as directed by your doctor. CLOBEX[®] Spray is for skin use only.
- Make sure your skin is clean and dry before applying CLOBEX[®] Spray.
- Apply CLOBEX[®] Spray twice a day, once in the morning and once at night, or as directed by your doctor. Use only enough to cover the affected skin areas and rub in gently and completely. Do not exceed 30 sprays per application or 60 sprays per day. **Do not apply CLOBEX[®] Spray to your face, underarms, or groin and avoid contact with eyes and lips.**
- Wash your hands after using CLOBEX[®] Spray.
- If you forget to apply CLOBEX[®] Spray 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 one 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[®] Spray.

What should I avoid while using CLOBEX[®] Spray?

Do not do the following while using CLOBEX[®] Spray.

- **Do not get CLOBEX[®] Spray on your face or lips, or in or near your eyes** because this might cause irritation. If you do, use a lot of water to rinse the CLOBEX[®] Spray 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[®] Spray 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[®] Spray any longer than 2 weeks (14 days)** for moderate to severe psoriasis.
 - **Do not use CLOBEX[®] Spray any longer than an extra 2 weeks (4 consecutive weeks total).**
 - **Do not use more than 50 grams (59 mL or 2 fluid ounces) of CLOBEX[®] Spray a week.**
- CLOBEX[®] Spray is available in a 2 oz. and 4.25 oz bottle.

What are the possible side effects of CLOBEX[®] Spray?

CLOBEX[®] Spray can pass through your skin. Too much CLOBEX[®] Spray passing through your skin can shut down your adrenal glands. This usually happens if you use too much CLOBEX[®] Spray, or you use it for too long. If this happens, your adrenal glands may not start working immediately once you stop using CLOBEX[®] Spray.

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 stress or illness. Your doctor may do special blood and urine tests to check your adrenal gland function while you are using CLOBEX[®] Spray.

Other possible side effects with CLOBEX[®] Spray include mild to moderate 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[®] Spray.

If you go to another doctor for illness, injury, or surgery, tell that doctor that you are using CLOBEX[®] Spray.

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[®] Spray.

These are not all the possible side effects of CLOBEX[®] Spray. For more information, ask your doctor or pharmacist.

General information about the safe and effective use of CLOBEX[®] Spray.

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

This leaflet summarizes the most important information about CLOBEX[®] Spray. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about CLOBEX[®] Spray that is written for health professionals.

What are the ingredients of CLOBEX[®] Spray?

Active Ingredient: clobetasol propionate

Inactive Ingredients: alcohol, isopropyl myristate, sodium lauryl sulfate, and undecylenic acid.

Rx Only

Marketed by:

GALDERMA LABORATORIES, L.P.

Fort Worth, Texas 76177 USA

Manufactured by:

CPL

Mississauga, Ontario, Canada L5N 6L6

Made in Canada.

GALDERMA is a registered trademark.

www.clobex.com

2004953-0409

Revised: April 2009

PRINCIPAL DISPLAY PANEL

Clobex®

(clobetasol propionate)

Spray

0.05%

2 FL OZ

(59 mL)



WARNING: FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.

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 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:** alcohol, isopropyl myristate, sodium lauryl sulfate, and undecylenic acid

Store at controlled room temperature 68° to 77°F (15° - 25°C), excursions permitted between 59° and 86°F (15° - 30°C). Protect from freezing. Keep out of reach of children.

US Patent Nos: 5,972,920; 5,990,100 and foreign patents pending.

CLOBEX

clobetasol propionate spray

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-5510(NDC:0299-3849-02)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CLOBETASOL PROPIONATE (UNII: 779619577M) (CLOBETASOL - UNII:ADN79D536H)			CLOBETASOL	0.5 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
ALCOHOL (UNII: 3K9958V90M)				
UNDECYLENIC ACID (UNII: K3D86KJ24N)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5510-0	59 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	NDA021835		01/23/2006	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel