NOTICE RECTO 180x315
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Clobex®

(clobetasol propionate) Shampoo, 0.05%

SHAMPOO

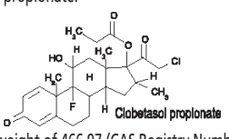
CLOBEX®
(clobetasol propionate) Shampoo, 0.05%
Rx Only
For External Use Only. Not for Ophthalmic Use.

DESCRIPTION: CLOBEX® (clobetasol propionate) Shampoo, 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.

The chemical name of clobetasol propionate is 21-chloro-9-fluoro-11ß, 17-dihydroxy-16ß-methylpregna-1, 4-diene-3, 20-dione 17-propionate.

It has the following structural formula:



Clobetasol propionate has a molecular weight of 466.97 (CAS Registry Number 25122-46-7). The molecular formula is $C_{25}H_{32}ClFO5$. Clobetasol propionate is a white to practically white crystalline, odorless powder insoluble in water.

Each mL of CLOBEX® (clobetasol propionate) Shampoo, 0.05%, contains clobetasol propionate, 0.05%, in a shampoo base consisting of alcohol, citric acid, coco-betaine, polyquaternium-10, purified water, sodium citrate, and sodium laureth sulfate. It is a translucent, colourless to pale yellow viscous liquid, with alcoholic odour.

CLINICAL PHARMACOLOGY: Like other topical corticosteroids, CLOBEX® (clobetasol propionate) Shampoo, 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 the 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 A_2.

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, while inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Due to the fact that circulating levels of corticosteroids are usually below the limit of detection following application, there are no human data regarding the pharmacokinetics of topical corticosteroids. In such cases pharmacodynamic end points, including both hypothalamic-pituitary-adrenal (HPA) axis testing and topical vasoconstriction, are used as surrogates in the assessments of systemic exposure and relative potency, respectively.

In studies evaluating the potential for hypothalamic-pituitary-adrenal (HPA) axis suppression, use of CLOBEX® (clobetasol propionate) Shampoo, 0.05%, resulted in demonstrable HPA axis suppression in 5 out of 12 (42%) adolescent patients (See PRECAUTIONS).

CLOBEX® Shampoo is in the high range of potency in vasoconstrictor studies.

CLINICAL STUDIES: The safety and efficacy of CLOBEX® (clobetasol propionate) Shampoo, 0.05%, has been evaluated in two clinical trials involving 290 adult patients with moderate to severe scalp psoriasis. In both trials, patients were treated with either CLOBEX® Shampoo or the corresponding vehicle applied once daily for 15 minutes before lathering and rinsing for a period of 4 weeks. Efficacy results are presented in the table below.

	CLOBEX® Shampoo n(%)		CLOBEX® Shampoo Vehicle n(%)	
	Study A	Study B	Study A	Study B
Total Number of Patients	95	99	47	49
Success Rate[1] -at Endpoint[2]	40 (42.1%)	28 (28.3%)	1 (2.1%)	5 (10.2%)
Subjects with Scalp Psoriasis Parameter Clear (None) at Endpoint				
Erythema[3]	17 (17.9%)	12 (12.1%)	3 (6.4%)	1 (2.0%)
Scaling[3]	21 (22.1%)	15 (15.2%)	0 (0%)	2 (4.1%)
Plaque Thickening[3]	35 (36.8%)	34 (34.3%)	5 (10.6%)	5 (10.2%)

[1] Success rate defined as the proportion of patients with a-0 (clear) or 1 (minimal) on a 0 to 5 point physician's Global Severity Scale for scalp psoriasis.

[2] At four (4) weeks or last observation recorded for a subject during the treatment period (baseline if no post-baseline data were available).

[3] Patients with 0 (clear) on a 0 to 3 point scalp psoriasis parameter scale.

Clinical studies of Clobetasol Propionate Shampoo, 0.05%, did not include sufficient numbers of non-Caucasian patients to determine whether they respond differently than Caucasian patients with regards to efficacy and safety.

INDICATIONS AND USAGE: CLOBEX® (clobetasol propionate) Shampoo, 0.05%, is a topical corticosteroid formulation indicated for the treatment of moderate to severe forms of scalp psoriasis in subjects 18 years of age and older (see PRECAUTIONS). Treatment should be limited to 4 consecutive weeks because of the potential for the drug to suppress the hypothalamic- pituitary-adrenal (HPA) axis. The total dosage should not exceed 50 g per week (see DOSAGE and ADMINISTRATION).

Patients should be instructed to use CLOBEX® Shampoo, 0.05%, for the minimum time period 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: Use of CLOBEX® (clobetasol propionate) Shampoo, 0.05%, is contraindicated in:
- Patients who are hypersensitive to clobetasol propionate, to other corticosteroids, or to any ingredient in this preparation.
- Skin areas affected by bacterial, viral, fungal, parasitic infections or ulcerous wounds.
- Children under 2 years of age
- Application to the eyes and eyelids (risk of glaucoma, risk of cataract)

PRECAUTIONS:

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

Topical corticosteroids are known to potentially induce:
- post treatment rebound, relapses upon discontinuation of treatment
- development of tolerance (tachyphylaxis)
- development of local toxicity such as skin atrophy, telangiectasia of the skin
- immunosuppression and opportunistic infections (including isolated cases of systemic infections), in case of prolonged use of potent topical corticosteroids in rare instances
- cataracts, when applied to eyes or eyelids
- Systemic absorption of topical corticosteroids has caused reversible adrenal suppression with the potential for glucocorticosteroid insufficiency, manifestations of Cushing's syndrome, hyperglycemia, and glycosuria in some patients.

Treatment of large surface areas, long-term continuous therapy with corticosteroids, use of occlusive dressings can enhance absorption and lead to a higher risk of systemic effects. Therefore, patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. If HPA axis 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. Abrupt discontinuation can lead to acute adrenal insufficiency, especially in children. Such systemic effects resolve when treatment is stopped. 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® (clobetasol propionate) Shampoo, 0.05% on HPA axis suppression was evaluated in one study in adolescents 12 to 17 years of age. In this study, 5 of 12 evaluable subjects developed suppression of their HPA axis following 4 weeks of treatment with CLOBEX® (clobetasol propionate) Shampoo, 0.05% applied once daily for 15 minutes to a dry scalp before lathering and rinsing.

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).

If irritation develops, CLOBEX® Shampoo should be discontinued and appropriate therapy instituted.

Hypersensitivity to corticosteroids can be observed.

Such an observation should be corroborated with appropriate diagnostic patch testing.

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® Shampoo should be discontinued until the infection has been adequately controlled.

Although CLOBEX® Shampoo is intended for the topical treatment of moderate to severe scalp psoriasis, it should be noted that certain areas of the body, such as the face, groin, and axillae, are more prone to atrophic changes than other areas of the body following treatment with corticosteroids. CLOBEX® Shampoo should not be used on the face and must not be applied on intertriginous areas such as groin or axillae. Avoid any contact of the drug product with the eyes and lips. In case of contact, rinse thoroughly with water all parts of the body that came in contact with the shampoo.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Cases of osteonecrosis, serious infections (including necrotizing fasciitis), and systemic immunosuppression (sometimes resulting in reversible Kaposi's sarcoma lesions) have been reported with long-term use of clobetasol propionate beyond the recommended doses (see Dosage and Administration). In some cases, patients used other potent oral/topical corticosteroids or immunosuppressors concomitantly (e.g. methotrexate, mycophenolate mofetil). If treatment with local corticosteroids is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered.

Information for patients: Patients using topical corticosteroids should receive the following information and instructions:
1. This medication is to be used as directed by the physician and should not be used longer than the prescribed time period. It is for external use only. Avoid contact with the eyes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The scalp area should not be covered while the medication is on the scalp (e.g., shower cap, bathing cap) so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local or systemic adverse reactions to their physician.
5. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.
6. Patients should wash their hands after applying the medication.
7. Patients should inform their physician(s) that they are using CLOBEX® Shampoo if surgery is contemplated.
8. Patients should not use more than 50 g (50 mL or 1.75 fl. oz.) per week of CLOBEX® Shampoo.

Laboratory tests: The cortrosyn 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 did not produce any increase in chromosomal aberrations in Chinese hamster ovary cells in vitro in the presence or absence of metabolic activation. Clobetasol propionate was also negative in the micronucleus test in mice after oral administration.

Studies of the effect of CLOBEX® (clobetasol propionate) Shampoo, 0.05% on fertility have not been conducted.

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.

A teratogenicity study of clobetasol propionate in rats using the dermal route resulted in dose related maternal toxicity and fetal effects from 0.05 to 0.5 mg/kg/day. These doses are approximately 0.1 to 1.0 times, respectively, the maximum human topical dose of clobetasol propionate from CLOBEX® Shampoo. Abnormalities seen included low fetal weights, umbilical herniation, cleft palate, reduced skeletal ossification other skeletal abnormalities. Clobetasol propionate administered to rats subcutaneously at a dose of 0.1 mg/kg from day 17 of gestation to day 21 postpartum was associated with prolongation of gestation, decreased number of offspring, increased perinatal mortality of offspring, delayed eye opening and delayed hair appearance in surviving offspring. Some increase in offspring perinatal mortality was also observed at a dose of 0.05 mg/kg. Doses of 0.05 and 0.1 mg/kg are approximately 0.1 and 0.2 fold the maximum human topical dose of clobetasol propionate from CLOBEX® Shampoo.

There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. CLOBEX® Shampoo 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 human milk. Because many drugs are excreted in human milk, caution should be exercised when CLOBEX® Shampoo, 0.05%, is administered to a nursing woman. Clobetasol propionate should not be prescribed to nursing women unless clearly indicated.

Galderma Laboratories

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Pediatric use: Use of CLOBEX® Shampoo, 0.05%, in patients under 18 years old is not recommended due to potential for HPA axis suppression (see PRECAUTIONS: General).
The effect of CLOBEX® (clobetasol propionate) Shampoo, 0.05%, on HPA axis suppression was evaluated in one study in adolescents 12 to 17 years of age. In this study, 5 of 12 evaluable subjects developed suppression of their HPA axis following 4 weeks of treatment with CLOBEX® (clobetasol propionate) Shampoo, 0.05%, applied once daily for 15 minutes to a dry scalp before lathering and rinsing. Only one of the five subjects who had suppression was tested for recovery of HPA axis, and this subject recovered after 2 weeks.
No studies have been performed in patients under the age of 12. 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 adrenal 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.
Therefore, use in patients between 2 and 18 years of age is not recommended and is contraindicated in children below 2 years of age.
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.

Geriatric use: Clinical studies of Clobetasol Propionate Shampoo, 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 clinical trials with CLOBEX® Shampoo, the following adverse reactions have been reported: burning/stinging, pruritus, edema, folliculitis, acne, dry skin, irritant dermatitis, alopecia, urticaria, skin atrophy and telangiectasia. The table below summarizes selected adverse events that occurred in at least 1% of subjects in the Phase 2 and 3 studies for scalp psoriasis.

Summary of Selected Adverse Events ≥ 1% by Body System

Body System	Clobetasol Propionate Shampoo N=558	Vehicle Shampoo N=127
Skin and Appendages	49 (8.8%)	28 (22.0%)
Discomfort Skin	26 (4.7%)	16 (12.6%)
Pruritus	3 (0.5%)	9 (7.1%)
Body As A Whole	33 (5.9%)	12 (9.4%)
Headache	10 (1.8%)	1 (0.8%)

The following additional local adverse reactions have been reported infrequently with other topical corticosteroids, and they may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximately decreasing order of occurrence: hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, miliaria, blurred vision. Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

System Organ Class	Frequency	Adverse reactions
Immune System Disorders	Uncommon	Hypersensitivity*
Endocrine disorders	Uncommon	Adrenal suppression* Cushing syndrome*
Nervous System disorders	Uncommon	Headache
Eye disorders	Uncommon	Eye stinging/burning Eye irritation Ocular discomfort Glaucoma*
	Not known	Vision, blurred (see also section 4.4)
Skin and subcutaneous tissue disorders	Common	Skin burning sensation, Folliculitis
	Uncommon	Pain of skin, Skin discomfort Pruritus Acne Skin oedema Telangiectasia Psoriasis (aggravation) Alopecia Dry skin Urticaria Skin atrophy Skin irritation Skin tightness
	Uncommon	Allergic contact dermatitis* Erythema* Rash*

* post marketing experience

OVERDOSAGE: Topically applied, CLOBEX® Shampoo can be absorbed in sufficient amounts to produce systemic effects. (See PRECAUTIONS).

In the case of chronic overdose or misuse, the features of hypercortisolism may appear and in this situation, treatment should be discontinued gradually. However, because of the risk of acute adrenal suppression, this should be done under medical supervision.

DOSAGE AND ADMINISTRATION: CLOBEX® Shampoo should be applied onto dry (not wet) scalp one application per day to the affected areas only, and left in place without covering for 15 minutes before rinsing with water.
Move the hair away from the scalp so that one of the affected areas is exposed. Position the bottle over the lesion. Apply a small amount of the shampoo directly onto the lesion, letting the product naturally flow from the bottle (gently squeeze the bottle), avoiding any contact of the product with the facial skin, eyes or lips. In case of contact, rinse thoroughly with water. Spread the product so that the entire lesion is covered with a thin uniform film. Massage gently into the lesion and repeat for additional lesion(s). Wash your hands after applying CLOBEX® Shampoo. Hands should be washed carefully after applications.
Avoid contact with eyes and lips. Minimize contact to non-affected areas of the body.
Although no additional shampoo is necessary to cleanse your hair, you may use a non-medicated shampoo if desired.

The treatment is limited to maximum 4 weeks. As with other corticosteroids, therapy should be discontinued when control is achieved. Clobetasol propionate belongs to the most potent class of topical corticosteroids and prolonged use may result in serious undesirable effects (see Precautions). If complete disease control is not achieved after 4 weeks of treatment with CLOBEX Shampoo 0.05%, and treatment with a topical corticosteroid is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered. Repeated but short courses of clobetasol propionate may be used to control exacerbations. If no improvement is seen within 4 weeks, reassessment of the diagnosis may be necessary. CLOBEX® Shampoo should not be used with occlusive dressings unless directed by a physician.

HOW SUPPLIED: CLOBEX Shampoo is supplied in 30ml, 60ml and 125ml bottles. Not all pack sizes may be marketed.
Storage: Keep tightly closed. Store below 30°C.

PATIENT INFORMATION
Read the Patient Information that comes with CLOBEX® Shampoo 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 the most important information I should know about CLOBEX® Shampoo?
What is CLOBEX® Shampoo?
CLOBEX® Shampoo is a medicine called a topical (skin use only) corticosteroid. It is used for a short time to treat forms of scalp psoriasis. CLOBEX® Shampoo is a highly potent (very strong) topical corticosteroid. It is very important that you use CLOBEX® Shampoo only as directed in order to avoid serious side effects.
Who should not use CLOBEX® Shampoo?
Do not use CLOBEX® Shampoo 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 a complete list of ingredients in CLOBEX® Shampoo. Ask your doctor or pharmacist if you need a list of other corticosteroids.
CLOBEX® Shampoo is not recommended for use by patients under 18 years of age. Children have smaller body sizes and have a higher chance of side effects.
What should I tell my doctor before using CLOBEX® Shampoo?
Tell your doctor:
- if you are pregnant, think you are pregnant, plan to be pregnant. Talk with your doctor before using CLOBEX® Shampoo or if you are already using CLOBEX® Shampoo. It is not known if CLOBEX® Shampoo can harm your unborn baby.
- if you are breastfeeding. It is not known if CLOBEX® Shampoo passes into your milk, and if it can harm your baby.
- if you think you have an infection on your scalp. You may need another medicine to treat the scalp infection before you use CLOBEX® Shampoo.

Tell your doctor about all the other medicines and skin products you use, including prescription and non-prescription medicines, vitamins, herbal supplements, and cosmetics. Some medicines and products can cause serious side effects if used while you are using CLOBEX® Shampoo.
How should I use CLOBEX® Shampoo?
- Use CLOBEX® Shampoo exactly as prescribed by your doctor. CLOBEX® Shampoo is for use on your scalp only.
- Apply CLOBEX® Shampoo on affected areas of the scalp once a day. Use only enough to cover the affected areas of your scalp. **Do not use CLOBEX® Shampoo on your face, groin, armpits, lips, or in your eyes.**
- Do not wet your hair before using CLOBEX® Shampoo. Move the hair away from the scalp so that one of the affected areas is exposed. Apply a small amount of the shampoo directly onto the affected area by gently squeezing the bottle. Gently, rub CLOBEX®Shampoo into the affected area. Repeat for other affected areas on your scalp.
- **Do not cover your head with a shower cap** or bathing cap while CLOBEX® Shampoo is on your scalp.
- Leave CLOBEX® Shampoo in place for 15 minutes before adding water, lathering and rinsing hair and scalp completely. No other shampoos are necessary. However, you can use a non-medicated shampoo on your hair after using CLOBEX® Shampoo if you want to.
- Wash your hands after applying CLOBEX® Shampoo. Wash any other part of your body that came into contact with CLOBEX® Shampoo such as your neck and shoulders.
- If you forget to apply CLOBEX® Shampoo 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 regular schedule. Do not make up the missed dose. If you miss several doses, tell your doctor.
- **Do not use more than 50 grams (50 mL or 1.75 fluid ounces) of CLOBEX® Shampoo per week.**

What should I avoid while using CLOBEX® Shampoo?
Do not do the following while using CLOBEX® Shampoo:
- **Do not get CLOBEX® Shampoo on your lips or in or near your eyes** because this might cause side effects. If you do, use a lot of water to rinse the CLOBEX® Shampoo off your face, lips, or out of your eyes. If your eyes keep stinging after rinsing them well with water, contact your doctor right away.
- **Do not apply CLOBEX® Shampoo to your face, groin or armpits.**
- **Do not get CLOBEX® Shampoo in your mouth.** If you or a child accidentally swallows CLOBEX Shampoo, call your Poison Control center or local emergency room right away.
- Do not cover your head with a shower or bathing cap while CLOBEX® Shampoo is on your scalp.
- **Do not use CLOBEX® Shampoo any longer than 4 weeks (28 days)** for moderate to severe scalp psoriasis.
- **Do not use more than 50 mL (1.75 fluid ounces) of CLOBEX® Shampoo per week.**

What should I do if I miss an application of CLOBEX® Shampoo?
If you forget to apply CLOBEX® Shampoo at the scheduled time, use it as soon as you remember, and then go back to your regular schedule. If you remember at the time of your next application, apply only one dose and continue with your regular schedule. If you miss several doses, tell your doctor.
What are the possible side effects of CLOBEX® Shampoo?
CLOBEX® Shampoo can pass through your skin. Too much CLOBEX® Shampoo passing through your skin can shut down your adrenal glands. This may happen if you use too much CLOBEX® Shampoo or if you use it for too long, but it can happen with correct use. If your adrenal glands shut down, they may not start working right away after you stop using CLOBEX® Shampoo. Shutting down of the adrenal glands can cause nausea, vomiting, fever, low blood pressure, heart attack and even death because your body cannot adequately 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® Shampoo.
The most common side effects with CLOBEX® Shampoo include burning or itching at the site of application. Other possible side effects include thinning of the skin, widening of small blood vessels in the skin, and blurred vision.
If you go to another doctor for illness, injury or surgery, tell that doctor that you are using CLOBEX® Shampoo.
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 healing after 4 weeks of using CLOBEX® Shampoo.

These are not all the possible side effects of CLOBEX® Shampoo. For more information, ask your doctor or pharmacist.
How should I store CLOBEX® Shampoo?
- Store CLOBEX® Shampoo below 30°C.
- Keep the bottle tightly closed at all times.
- Do not use CLOBEX® Shampoo after the expiration date shown on bottle.
- **Keep CLOBEX® Shampoo and all medicines out of the reach of children.**

General information about CLOBEX® Shampoo
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use CLOBEX® Shampoo for a condition for which it was not prescribed. Do not give CLOBEX® Shampoo to other people, even if they have the same symptoms you have. It may harm them. This leaflet summarizes the most important information about CLOBEX® Shampoo. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about CLOBEX® Shampoo that is written for health professionals.
What are the ingredients in CLOBEX® Shampoo?
Active ingredient: clobetasol propionate
Excipients (shampoo base):
alcohol, citric acid, coco-betaine, polyquaternium-10, purified water, sodium citrate and sodium laureth sulfate.
Rx Only
Manufactured by:
Laboratoires Galderma
Z.I Montdésir
74540 Alby-sur-Chéran
France
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