

- **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 and widening of small blood vessels in the skin.

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 at room temperature between 68°F to 77°F (20°C - 25°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

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

Manufactured by:
DPT Laboratories, Ltd.
San Antonio, Texas 78215 USA
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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.

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 is not recommended in patients under the age of 18.

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, and miliaria.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

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

DOSAGE AND ADMINISTRATION: CLOBEX® Shampoo should be applied onto dry (not wet) scalp once a day in a thin film to the affected areas only, and left in place for 15 minutes before lathering and rinsing.

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.

Leave the shampoo in place for 15 minutes, then add water, lather and rinse thoroughly all parts of the scalp and body that came in contact with the shampoo (e.g., hands, face, neck and shoulders). 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.

Treatment should be limited to 4 consecutive weeks. As with other corticosteroids, therapy should be discontinued when control is achieved. If complete disease control is not achieved after four weeks of treatment with CLOBEX® Shampoo, 0.05%, treatment with a less potent topical steroid may be substituted. 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 4 fl.oz. (118 mL) bottles.
NDC 0299-3847-04

Storage: Keep tightly closed. Store at controlled room temperature 68°F to 77°F (20°C-25°C).

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