Apply Taclonex® Topical Suspension in 3 steps

Once daily for your plaque psoriasis[1]

1 Shake

- Be sure to shake the Taclonex® Topical Suspension bottle before each application

2 Squeeze

- Remove the cap and squeeze a small amount of Taclonex® Topical Suspension onto the tip of your finger

3 Apply

For the scalp* *(adult and adolescent patients)*:

- Part your hair in affected areas and apply Taclonex® Topical Suspension directly on scalp plaques
- Always wash your hands immediately after applying Taclonex® Topical Suspension
- **Do not** wash your hair right after applying Taclonex® Topical Suspension

- **Do not** apply Taclonex® Topical Suspension to the scalp in the 12 hours before or after any chemical treatment to the hair

For the body* *(adult patients)*:

- Gently rub the drop of Taclonex® Topical Suspension onto affected areas of skin
- Always wash your hands immediately after applying Taclonex® Topical Suspension

*Use Taclonex® Topical Suspension exactly as your doctor tells you to use it.

INDICATION AND USAGE

Taclonex® Topical Suspension is indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 18 years and older and for plaque psoriasis of the scalp in patients 12 to 17 years. Apply Taclonex® Topical Suspension to affected areas once daily for up to 8 weeks. Therapy should be discontinued when control is achieved. Patients 18 years and older should not use more than 100 g per week and patients 12 to 17 years should not use more than 60 g per week.

Please see reverse for Important Safety Information.

Taclonex®
(calcipotriene and betamethasone dipropionate) Topical Suspension
0.005%/0.064%

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IMPORTANT SAFETY INFORMATION

FOR TOPICAL USE ONLY. Taclonex® Topical Suspension is not for oral, ophthalmic, or intravaginal use and should not be applied to the face, axillae, or groin. Do not use if atrophy is present at the treatment site. Do not use with occlusive dressings unless directed by a physician.

Hypercalcemia and hypercalciuria have been observed with use of Taclonex®. If hypercalcemia or hypercalciuria develop, discontinue treatment until parameters of calcium metabolism have normalized. Taclonex® can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for clinical glucocorticosteroid insufficiency. Use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression and calcium abnormalities. If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent steroid. Cushing's syndrome and hyperglycemia may also occur in adults due to the systemic effects of the topical corticosteroid. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of systemic toxicity, HPA axis suppression and adrenal insufficiency. Rare systemic toxicities such as Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients.

In clinical trials, the most common adverse reactions that occurred in ≥1% of subjects treated with Taclonex® and at a rate higher than in subjects treated with vehicle were folliculitis and burning sensation of skin. Other less common adverse reactions (<1% but >0.1%) were, in decreasing order of incidence: acne, exacerbation of psoriasis, eye irritation, and pustular rash. Local adverse reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform dermatitis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria and may be more likely with occlusive use or more potent corticosteroids.

Taclonex® may cause eye irritation. Avoid eye exposures. Patients who apply Taclonex® to exposed skin should avoid excessive exposure to either natural or artificial sunlight, including tanning booths, sun lamps, etc. There are no adequate and well-controlled studies of Taclonex® Topical Suspension in pregnant women. Taclonex® should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus. Because many drugs are excreted in human milk, caution should be exercised when Taclonex® Topical Suspension is administered to a nursing woman. The patient should be instructed not to use Taclonex® Topical Suspension on the breast when nursing. Safety and effectiveness of the use of Taclonex® Topical Suspension in pediatric patients under the age of 12 years have not been established.

Please see accompanying full Prescribing Information.

Reference:
1. Taclonex® Topical Suspension [package insert], Parsippany, NJ: LEO Pharma Inc; August 2014.

LEO®

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