

**PATIENT INFORMATION**  
**Taclonex<sup>®</sup> (TAK-lo-NEKS)**  
**(calcipotriene and betamethasone dipropionate)**  
Topical Suspension, 0.005%/0.064%

**Important:** Taclonex<sup>®</sup> Topical Suspension is for use on skin only (topical). Do not get Taclonex<sup>®</sup> Topical Suspension near or in your mouth, eyes, or vagina.

There are other medicines that contain the same medicine that is in Taclonex<sup>®</sup> Topical Suspension and are used to treat plaque psoriasis. Do not use other products containing calcipotriene or a corticosteroid medicine with Taclonex<sup>®</sup> Topical Suspension without talking to your doctor first.

**What is Taclonex<sup>®</sup> Topical Suspension?**

Taclonex<sup>®</sup> Topical Suspension is a prescription medicine used on the skin only (topical use) to treat:

- plaque psoriasis of the scalp and body in adults 18 years of age and older
- plaque psoriasis of the scalp in children from 12 to 17 years of age

It is not known if Taclonex<sup>®</sup> Topical Suspension is safe and effective in children under 12 years of age.

**What should I tell my doctor before using Taclonex<sup>®</sup> Topical Suspension?**

**Before you use Taclonex<sup>®</sup> Topical Suspension, tell your doctor about all of your medical conditions, including if you:**

- have a calcium metabolism disorder.
- have thinning-skin (atrophy) at the site to be treated.
- are getting light therapy (phototherapy treatments) for your psoriasis
- are pregnant or plan to become pregnant. It is not known if Taclonex<sup>®</sup> Topical Suspension will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Taclonex<sup>®</sup> Topical Suspension passes into your breast milk. You should not use Taclonex<sup>®</sup> Topical suspension on your breast if you breastfeed.

**Tell your doctor about all the medicines you take, including prescription and over-the counter medicines, vitamins, and herbal supplements.**

**How should I use Taclonex<sup>®</sup> Topical Suspension?**

**See the “Instructions for Use” for detailed information about the right way to use Taclonex<sup>®</sup> Topical Suspension .**

- Use Taclonex<sup>®</sup> Topical Suspension exactly as your doctor tells you to use it.
- Your doctor should tell you how much Taclonex<sup>®</sup> Topical Suspension to use and where to use it.
- Taclonex<sup>®</sup> Topical Suspension comes in:
  - a carton containing a 60 g bottle or a carton containing 120 g (2 bottles of 60 g)
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- If you are 18 years of age or older, you should not use more than 100 grams of Taclonex<sup>®</sup> Topical Suspension in **1 week**.
- If you are 12 to 17 years of age, you should not use more than 60 grams of Taclonex<sup>®</sup> Topical Suspension in **1 week**.
- Do not use Taclonex<sup>®</sup> Topical Suspension longer than prescribed. Using too much Taclonex<sup>®</sup> Topical Suspension, or using it too often, or for too long can increase your risk for having serious side effects.
- Apply Taclonex<sup>®</sup> Topical Suspension to affected areas on the skin 1 time a day for up to 8 weeks. You should stop treatment when your plaque psoriasis is under control, unless your doctor gives you other instructions.
- Do not apply Taclonex<sup>®</sup> Topical Suspension to the scalp in the 12 hours before or after any chemical treatments to your hair. Since hair treatments may involve strong chemicals, talk with your doctor first.
- If you accidentally get Taclonex<sup>®</sup> Topical Suspension on your face or in your eyes, wash the area with water right away.
- Avoid using Taclonex<sup>®</sup> Topical Suspension on your face, groin, or armpits (axilla), or if you have thinning of your skin (atrophy) at the treatment site.
- Do not wash your hair, take a bath, or shower right after applying Taclonex<sup>®</sup> Topical Suspension as the medicine will not work as well to treat your psoriasis.

- **Do not bandage or cover the treated skin area, unless instructed by your doctor.**

#### **What should I avoid while using Taclonex<sup>®</sup> Topical Suspension?**

**Avoid spending a long time in sunlight. Avoid tanning booths and sun lamps.**

#### **What are the possible side effects of Taclonex<sup>®</sup> Topical Suspension?**

**Taclonex<sup>®</sup> Topical Suspension may cause serious side effects, including:**

- too much calcium in your blood or urine**
- adrenal gland problems**

Your doctor may do blood and urine tests to check your calcium levels and adrenal gland function while you are using Taclonex<sup>®</sup> Topical Suspension.

- skin problems such as**
  - **thinning of your skin**
  - **burning**
  - **inflammation**
  - **itching**
  - **irritation**
  - **dryness**
  - **changes in skin color**
  - **redness**
  - **infection**
  - **raised bumps on your skin**

- **eye irritation if you accidentally get Taclonex<sup>®</sup> Topical Suspension in your eyes**

**The most common side effects of Taclonex<sup>®</sup> Topical Suspension are inflamed hair pores (folliculitis) and skin burning.**

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Taclonex<sup>®</sup> Topical Suspension. For more information, ask your doctor or pharmacist.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

#### **How should I store Taclonex<sup>®</sup> Topical Suspension?**

- Store Taclonex<sup>®</sup> Topical Suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not refrigerate **Taclonex<sup>®</sup> Topical Suspension**.
- Keep the bottle in the outer carton when not in use.
- Discard unused Taclonex<sup>®</sup> Topical Suspension 6 months after it has been opened.

**Keep Taclonex<sup>®</sup> Topical Suspension and all medicines out of the reach of children.**

#### **General information about Taclonex<sup>®</sup> Topical Suspension.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Taclonex<sup>®</sup> Topical Suspension for a condition for which it was not prescribed. Do not give Taclonex<sup>®</sup> Topical Suspension to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about Taclonex<sup>®</sup> Topical Suspension. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Taclonex<sup>®</sup> Topical Suspension that is written for health professionals.

#### **What are the ingredients in Taclonex<sup>®</sup> Topical Suspension?**

**Active ingredients:** calcipotriene hydrate and betamethasone dipropionate.

**Inactive ingredients:** hydrogenated castor oil, polyoxypropylene stearyl ether, all-rac-alpha-tocopherol, butylhydroxytoluene and mineral oil.

Manufactured by: LEO Laboratories Ltd., 285 Cashel Road, Dublin 12, Ireland

Distributed by: LEO Pharma Inc., 1 Sylvan Way, Parsippany, NJ 07054, USA

For more information, go to [www.taclonex.com](http://www.taclonex.com) or call 1-877-494-4536.

This Patient Information has been approved by the U.S. Food and Drug Administration.