

PATIENT INFORMATION
Taclonex[®] (TAK-lo-NEKS)
(calcipotriene and betamethasone dipropionate)
Topical Suspension, 0.005%/0.064%

Important: Taclonex[®] Topical Suspension is for use on skin only (topical). Do not get Taclonex[®] Topical Suspension near or in your mouth, eyes, or vagina.

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

What is Taclonex[®] Topical Suspension?

Taclonex[®] 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[®] Topical Suspension is safe and effective in children under 12 years of age.

What should I tell my doctor before using Taclonex[®] Topical Suspension?

Before you use Taclonex[®] 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[®] Topical Suspension will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Taclonex[®] Topical Suspension passes into your breast milk. You should not use Taclonex[®] 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[®] Topical Suspension?

See the “Instructions for Use” for detailed information about the right way to use Taclonex[®] Topical Suspension.

- Use Taclonex[®] Topical Suspension exactly as your doctor tells you to use it.
- Your doctor should tell you how much Taclonex[®] Topical Suspension to use and where to use it.
- Taclonex[®] Topical Suspension comes in:
 - a carton containing a 60 g bottle or a carton containing 120 g (2 bottles of 60 g)
- If you are 18 years of age or older, you should not use more than 100 grams of Taclonex[®] Topical Suspension in **1 week**.
- If you are 12 to 17 years of age, you should not use more than 60 grams of Taclonex[®] Topical Suspension in **1 week**.
- Do not use Taclonex[®] Topical Suspension longer than prescribed. Using too much Taclonex[®] Topical Suspension, or using it too often, or for too long can increase your risk for having serious side effects.
- Apply Taclonex[®] 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[®] 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[®] Topical Suspension on your face or in your eyes, wash the area with water right away.
- Avoid using Taclonex[®] 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[®] 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[®] Topical Suspension?

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

What are the possible side effects of Taclonex[®] Topical Suspension?

Taclonex[®] 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[®] 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[®] Topical Suspension in your eyes

The most common side effects of Taclonex[®] 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[®] 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[®] Topical Suspension?

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

Keep Taclonex[®] Topical Suspension and all medicines out of the reach of children.

General information about Taclonex[®] Topical Suspension.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Taclonex[®] Topical Suspension for a condition for which it was not prescribed. Do not give Taclonex[®] 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[®] Topical Suspension. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Taclonex[®] Topical Suspension that is written for health professionals.

What are the ingredients in Taclonex[®] 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., Seven Giralda Farms, Madison, NJ 07940, USA
For more information, go to www.taclonex.com or call 1-877-494-4536.