Taclonex® (TAK-lo-NEKS) (calcipotriene and betamethasone dipropionate) Topical Suspension

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 healthcare provider first.

What is Taclonex Topical Suspension?
Taclonex Topical Suspension is a prescription medicine used on the skin (topical) to treat plaque psoriasis of the scalp and body in people 12 years and older.

It is not known if Taclonex Topical Suspension is safe and effective in children under 12 years of age.

Before you use Taclonex Topical Suspension, tell your healthcare provider about all of your medical conditions, including if you:
• have a calcium metabolism disorder.
• have thinning skin (atrophy) at the treatment site.
• are pregnant or plan to become pregnant. It is not known if Taclonex Topical Suspension will harm your unborn baby. Taclonex Topical Suspension may increase your chance of having a low birth weight baby. If you use Taclonex Topical Suspension during pregnancy, use Taclonex Topical Suspension on the smallest area of the skin and for the shortest time needed.
• are breastfeeding or plan to breastfeed. It is not known if Taclonex Topical Suspension passes into your breast milk. Breastfeeding women should use Taclonex Topical Suspension on the smallest area of the skin and for the shortest time needed. Do not apply Taclonex Topical Suspension directly to the nipple and areola to avoid contact with your baby.

Tell your healthcare provider 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 healthcare provider tells you to use it.
• Your healthcare provider should tell you how much Taclonex Topical Suspension to use and where to use it.
• Apply Taclonex Topical Suspension to affected areas on the scalp and body 1 time a day for up to 8 weeks. You should stop treatment when your plaque psoriasis is under control, unless your healthcare provider gives you other instructions.
• If you are 12 to 17 years of age, you should not use more than 60 grams of Taclonex Topical Suspension in 1 week.
• If you are 18 years of age or older, you should not use more than 100 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.
• 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 healthcare provider first.
• Do not use Taclonex Topical Suspension in the mouth, eyes, or vagina.
• Do not use Taclonex Topical Suspension on your face, groin, or armpits, or if you have thinning of your skin (atrophy) at the treatment site.
• If you accidentally get Taclonex Topical Suspension on your face or in your eyes, wash the area with water right away.
• Wash your hands after applying Taclonex Topical Suspension.
• Do not take a bath or shower or wash your hair 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 healthcare provider.
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.** Your healthcare provider may tell you to stop or temporarily stop treatment with Taclonex Topical Suspension if you have too much calcium in your blood or urine.
- **Taclonex Topical Suspension can pass through your skin.** Too much Taclonex Topical Suspension passing through your skin can cause your adrenal glands to stop working properly. Your healthcare provider may do blood tests to check for adrenal gland problems.
- **Cushing’s syndrome,** a condition that happens when your body is exposed to large amounts of the hormone cortisol.
- **High blood sugar (hyperglycemia).**
- **Skin problems.** Tell your healthcare provider if you have any skin problems, including:
  - thinning of your skin
  - dryness
  - burning
  - changes in skin color
  - inflammation
  - redness
  - itching
  - infection
  - irritation
  - raised bumps on your skin
- **Eye problems.** Using Taclonex Topical Suspension may increase your chance of getting cataracts and glaucoma. Do not get Taclonex Topical Suspension in your eyes because it may cause eye irritation. Tell your healthcare provider if you have blurred vision or other vision problems during treatment with Taclonex Topical Suspension.

The most common side effects of Taclonex Topical Suspension include inflamed hair pores (folliculitis) and skin burning.

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 carton when not in use.
- Throw away (discard) unused Taclonex Topical Suspension 6 months after it has been opened.

Keep Taclonex Topical Suspension and all medicines out of 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.

You can ask your pharmacist or healthcare provider for information about Taclonex Topical Suspension that is written for health professionals.

What are the ingredients in Taclonex Topical Suspension?

**Active ingredients:** calcipotriene 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., Madison, NJ 07940, USA
For more information, go to www.taclonex.com or call 1-877-494-4536.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 7/2019
INSTRUCTIONS FOR USE
TACLONEX® (TAK-lo-NEKS)
(calcipotriene and betamethasone dipropionate)
Topical Suspension

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Read this Instructions for Use before you start using Taclonex Topical Suspension and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

How to apply Taclonex Topical Suspension to your body:
Follow your healthcare provider’s instructions of how much Taclonex Topical Suspension to use and where to use it. Apply Taclonex Topical Suspension directly to areas affected by plaque psoriasis and gently rub in. Wash your hands after applying Taclonex Topical Suspension, unless you are treating areas on your hands.

How to apply Taclonex Topical Suspension to your scalp:
You do not need to wash your hair before you apply Taclonex Topical Suspension.

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<thead>
<tr>
<th>Step 1: Shake the bottle before use. Remove the cap from the bottle. (See Figure A).</th>
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<tbody>
<tr>
<td>Step 2: Locate the area to treat using your fingers and part your hair. (See Figure B).</td>
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<tr>
<td>Step 3: Squeeze a drop of Taclonex Topical Suspension to your fingertip. (See Figure C).</td>
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<tr>
<td>Step 4: Use your fingers to apply the drop of Taclonex Topical Suspension directly to scalp affected by plaque psoriasis. Gently rub in. (See Figure D).</td>
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<tr>
<td>Step 5: After applying Taclonex Topical Suspension, put the cap back on the bottle.</td>
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<tr>
<td>Step 6: Wash your hands after applying Taclonex Topical Suspension. Do not wash your hair right after you apply Taclonex Topical Suspension to your scalp.</td>
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