

17.5 FDA-Approved Patient Labeling

Patient Information

Taclonex[®] Ointment (pronounced TAK-lo-NEKS) (calcipotriene 0.005% and betamethasone dipropionate 0.064%)

Read the Patient Information that comes with Taclonex[®] Ointment before you start using it and each time you refill your prescription. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

Important information: Taclonex[®] Ointment is for use on the skin only (topical use only). Do not use Taclonex[®] Ointment on the face, under arms or on groin area. **Do not swallow Taclonex[®] Ointment.** Another product, Taclonex Scalp[®] Topical Suspension contains the same medicine that is in Taclonex[®] Ointment and is used to treat psoriasis vulgaris on the scalp. If you use both medicines to treat your psoriasis vulgaris, be sure to follow your doctor's directions carefully so that you do not use too much of one or both of these medications.

What is Taclonex[®] Ointment?

Taclonex[®] Ointment is a prescription medicine that is for use on the skin only (a topical medicine). Taclonex[®] Ointment is used to treat psoriasis vulgaris in adults 18 years of age and older.

Taclonex[®] Ointment is not recommended for use in children. Taclonex[®] Ointment has not been studied in patients under the age of 18.

Who should not use Taclonex[®] Ointment?

Do not use Taclonex[®] Ointment if you:

- **have a calcium metabolism disorder**
- **have one of the following types of psoriasis:**
 - o erythrodermic psoriasis
 - o exfoliative psoriasis
 - o pustular psoriasis
- have severe kidney or liver disease
- **are allergic to anything in Taclonex[®] Ointment.** See the end of this leaflet for a complete list of ingredients.

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

Tell your doctor about all of your health conditions, including if you:

- **have a skin infection.** Your skin infection should be treated before starting Taclonex[®] Ointment.
- **have thin-skin (atrophy) at the site to be treated.** You should not use Taclonex[®] Ointment.
- **are getting phototherapy treatments (light therapy) for your psoriasis.**
- **are pregnant or planning to become pregnant.** It is not known if Taclonex[®] Ointment can harm your unborn baby. You and your doctor will have to decide if Taclonex[®] Ointment is right for you while pregnant.
- **are breastfeeding.** It is not known if Taclonex[®] Ointment passes into your milk and if it can harm your baby.

Tell your doctor about all the medicines you take, including prescription, and nonprescription medicines, vitamins and herbal supplements. Taclonex[®] Ointment and some other medicines can interact with each other. Especially tell your doctor if you use:

- other corticosteroid medicines
- other medicines for your psoriasis

How should I use Taclonex[®] Ointment?

- Use Taclonex[®] Ointment exactly as prescribed by your doctor.
- Do not use more than the maximum recommended weekly amount of 100 grams of Taclonex[®] Ointment.
- Apply Taclonex[®] Ointment once a day to the areas of your skin affected by psoriasis. Gently rub Taclonex[®] Ointment into your affected skin areas.
- Only use Taclonex[®] Ointment as directed by your doctor. Taclonex[®] Ointment is recommended for up to 4 weeks of treatment.

Do not use Taclonex[®] Ointment for more than 4 weeks unless prescribed by your doctor.

- Do not use Taclonex[®] Ointment on the face, under arms or on groin area. If you accidentally get Taclonex[®] Ointment on the face or in the eyes wash the area with water right away.
- If you forget to use Taclonex[®] Ointment, use it as soon as you remember. Then go on as before.

- Wash your hands well after applying Taclonex[®] Ointment.

Using Taclonex[®] Ointment:

Do not bandage or tightly cover the treated skin area.

Remove the cap and check that the aluminum seal covers the tube before the first use. To break the seal, turn the cap over and punch through the seal.

What should I avoid while using Taclonex[®] Ointment?

Avoid spending a long time in the sunlight. Avoid tanning booths and sunlamps. Use sunscreen if you have to be in the sunlight. Talk to your doctor if you get a sunburn.

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

The most common side effects are:

- itching
- rash

Other less common side effects with Taclonex[®] Ointment include:

- redness of the skin
- skin irritation
- skin burning
- inflamed hair pores (folliculitis)
- change of skin color (at the site of application)
- rash with pus-filled papules
- thinning of the skin (atrophy)
- swollen fine blood vessels (this makes your skin appear red at the site of application)

Taclonex[®] Ointment may cause serious side effects. Serious side effects are more likely to happen if you use too much Taclonex[®] Ointment, use it for too long, or use it with other topical medicines that contain corticosteroids, calcipotriene, or certain other ingredients. Check with your doctor before using other topical medicines. Taclonex[®] Ointment can pass through your skin. Serious side effects may include:

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

Your doctor may do special blood and urine tests to check your calcium levels and adrenal gland function while you are using Taclonex[®] Ointment.

Call your doctor about any side effect that bothers you or that does not go away.

These are not all of the side effects with Taclonex[®] Ointment. Ask your doctor or pharmacist for more information.

How should I store Taclonex[®] Ointment?

- Store Taclonex[®] Ointment between 68 - 77° F (20 - 25° C); excursions permitted between 59 - 86° F (15 - 30° C).
- Make sure the cap on the tube is tightly closed.
- Taclonex[®] Ointment has an expiration date (exp.) marked on the tube. Do not use the ointment after this date.
- **Keep Taclonex[®] Ointment and all medicines out of the reach of children and pets.**

General information about Taclonex[®] Ointment

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Taclonex[®] Ointment for a condition for which it was not prescribed. Do not give Taclonex[®] Ointment 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[®] Ointment. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Taclonex[®] Ointment that is written for health professionals.

What are the ingredients in Taclonex[®] Ointment?

Active ingredients: calcipotriene hydrate, betamethasone dipropionate.

Inactive ingredients: mineral oil, PPG-15 stearyl ether, dl-alpha tocopherol, white petrolatum.



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