

## PART III: CONSUMER INFORMATION

<sup>PR</sup>DOVONEX® Scalp Solution  
calcipotriol

This leaflet is part III of a three-part "Product Monograph" published when DOVONEX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DOVONEX. Contact your doctor or pharmacist if you have any questions about this drug. This leaflet is also available on-line at [www.dovonex.ca](http://www.dovonex.ca).

**ABOUT THIS MEDICATION**What the medication is used for:

- DOVONEX scalp solution is used for the topical treatment of scalp psoriasis.
- DOVONEX scalp solution is not for use on the face.

What it does:

DOVONEX contains the active ingredient calcipotriol, a vitamin D-like agent.

Psoriasis results from skin cells growing and dividing too quickly, causing plaques (scaly, red patches) to form on the skin. Calcipotriol comes from naturally occurring vitamin D and acts to return the growth of skin cells to normal.

When it should not be used:

- Do not use this product if you are allergic to any of the ingredients in DOVONEX (calcipotriol) scalp solution, or to components of the container.
- DOVONEX scalp solution is not for use in your eyes.

What the medicinal ingredient is:

Calcipotriol

What the important nonmedicinal ingredients are:

Scalp solution: hydroxypropyl cellulose, isopropanol, levomenthol, sodium citrate, propylene glycol, purified water.

What dosage forms it comes in:

DOVONEX is available as a 50 mcg/mL scalp solution.

**WARNINGS AND PRECAUTIONS**

Calcipotriol when used with ultraviolet radiation (UVR) may increase the risk of developing skin cancer caused by UVR. Calcipotriol alone does not cause cancer.

If DOVONEX is used together with other psoriasis treatments, you should read the warning section of the consumer information for those treatments.

DOVONEX is not recommended for your face as it may cause skin irritation.

The scalp solution is not recommended for use in children under 18 years old.

DOVONEX should only be used during pregnancy or while nursing if the benefit clearly outweighs the potential risk to your baby. Tell your doctor if you are pregnant, nursing, or become pregnant during your treatment.

If more than the maximum recommended weekly amount of DOVONEX (cream, ointment, scalp solution) is used (i.e., 100 g), there is the risk of developing high blood calcium levels.

**BEFORE** you use DOVONEX scalp solution talk to your doctor or pharmacist if:

- you are using any other psoriasis treatments.
- you are using sun tanning beds or sun lamps.
- you are currently using phototherapy for your psoriasis.
- you have allergies to any of the ingredients in DOVONEX scalp solution or to components of the container.

**INTERACTIONS WITH THIS MEDICATION**

There is no clinical trial experience on the interaction of DOVONEX scalp solution with other topical drugs for scalp psoriasis.

**PROPER USE OF THIS MEDICATION**Usual dose:

At the start of your treatment DOVONEX scalp solution should be rubbed onto affected scalp areas twice a day (morning and evening). You should begin to see an improvement within 2 weeks. Best results are seen within 6-8 weeks.

Once your psoriasis improves your doctor may reduce the dose to once a day. Using DOVONEX scalp solution once a day will help keep your psoriasis under control.

How to use the scalp solution:

*The instructions below are for adults only, the scalp solution is not recommended for use in children under 18 years old.*

- After washing your hair, dry it thoroughly before using DOVONEX scalp solution. Do not wash your hair immediately after using the scalp solution or you will wash out the medicine.
- Remove cap, place the nozzle through your hair next to the scalp. Squeeze the bottle gently and apply a few drops on to the affected area.
- Rub in gently with your fingertips. One or two drops should cover the area of a postage stamp.
- Wash your hands after using DOVONEX scalp solution to avoid getting any on your face.
- DOVONEX scalp solution may irritate your scalp for a short time after you apply it. Try not to scratch the area.

- DOVONEX scalp solution should not be used on your face because it could irritate your skin. If you accidentally get some on your face, wash it off right away. If you get the scalp solution in your eyes, flush your eyes with water.
- Do not use more than 60 mL of DOVONEX scalp solution in one week.
- If you use the scalp solution in combination with DOVONEX cream or ointment then the total amount of DOVONEX products used (grams + mLs) should not be greater than 100.

*For example, if you use 60 g of cream or ointment per week, then you should not use more than 40 mL of scalp solution per week.*

**Overdose:**

The calcipotriol in DOVONEX can lead to increased blood calcium levels if more than the maximum 100 g weekly amount is used. This effect is reversible when treatment is stopped. If you have overdosed, contact your Doctor or go to the nearest Hospital Emergency.

**Missed Dose:**

If you forget to use DOVONEX at the right time, use it as soon as you remember. Then go on as before.

pharmacist.

**HOW TO STORE IT**

Scalp Solution: Store below 25°C. Use within 3 months of first opening the bottle.

- Keep DOVONEX in a safe place where children cannot reach it.
- Keep DOVONEX away from your pets. Dogs like the taste of DOVONEX but the medicine can be fatal to dogs if swallowed. If your dog swallows DOVONEX contact a veterinarian immediately.
- Do not use DOVONEX past the expiry date marked on the bottle.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345  
 By toll-free fax: 1-866-678-6789  
 Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
 By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:  
 Canada Vigilance National Office  
 Marketed Health Products Safety and Effectiveness  
 Information Bureau Marketed Health Products Directorate  
 Health Products and Food Branch  
 Health Canada  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: If you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.*

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The most common side effect is local irritation which is usually mild and temporary.

Facial irritation is usually related to the accidental transfer of DOVONEX scalp solution from the scalp. Rare cases of allergic reaction have been reported.

Use of calcipotriol can lead to high blood calcium levels but this is usually related to using more than the weekly maximum.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very rarely:  Hypercalcaemia (high blood calcium levels)	Fatigue, depression mental confusion, anorexia, nausea, vomiting, constipation, increased urination and in some patients, cardiac arrhythmias	✓		✓

*This is not a complete list of side effects. For any unexpected effects while taking DOVONEX, contact your doctor or*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: [www.leo-pharma.com/canada](http://www.leo-pharma.com/canada) or by contacting the sponsor, LEO Pharma Inc. at: 1-800-668-7234.

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This leaflet was prepared by LEO Pharma Inc.  
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