

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **DOVONEX**[®]

Calcipotriol ointment

Read this carefully before you start taking **DOVONEX** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DOVONEX**.

What is **DOVONEX** used for?

- **DOVONEX** is used in children (2 to 14 years of age) and adults (14 to 65 years of age) for the topical (for the skin) treatment of psoriasis on your body. Psoriasis is a chronic skin disease.
- **DOVONEX** may be used together with moderate to very strong topical corticosteroid, cyclosporin A (oral) or acitretin (oral) drugs.

DOVONEX is not for use on the face.

How does **DOVONEX** work?

DOVONEX contains the medicinal ingredient calcipotriol. Calcipotriol comes from naturally occurring vitamin D. Psoriasis is a condition when the cells in your skin grow too much. This can cause plaques (scaly, red patches) to form on the skin. Calcipotriol, like Vitamin D, controls how the cells in your skin grow. Calcipotriol is believed to work by reducing the growth of skin cells to a normal level.

What are the ingredients in **DOVONEX**?

Medicinal ingredients: calcipotriol

Non-medicinal ingredients: disodium edetate, disodium phosphate dihydrate, DL- α -tocopherol, liquid paraffin, polyoxyethylene-(2)-stearyl ether, propylene glycol, purified water, white soft paraffin.

DOVONEX comes in the following dosage forms:

Ointment (50 mcg/g)

Do not use **DOVONEX** if:

- You are allergic to any of the ingredients in **DOVONEX**, or to components of the container.
- You have high or low levels of calcium in your body (calcium metabolism disorder).
- You are pregnant

DOVONEX is not for use in your eyes.

You may be taking **DOVONEX** with other medications to treat psoriasis. Please read the Patient Medication Information of those particular medicines. The Patient Medication Information for those medicines should be considered and followed when taking **DOVONEX**.

To find this information:

- go online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug->

[products/drug-product-database.html](#)

-contact your healthcare professional

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DOVONEX. Talk about any health conditions or problems you may have, including if:

- You have severe psoriasis or large areas of the body with psoriasis. The use of DOVONEX may not be recommended due to the risk of developing hypercalcemia (high calcium levels in the blood). You are more likely to have high calcium levels in your blood if you use more than the recommended weekly dose prescribed by your healthcare professional. Your healthcare professional will examine calcium levels before and during treatment with DOVONEX. Your healthcare professional may end your treatment with DOVONEX if your blood tests show you have high calcium levels.
- You have other types of psoriasis (i.e. guttate, erythrodermic, pustular)
- You are using phototherapy or any other psoriasis treatments.
- You are using sun tanning beds or sun lamps.

Other warnings you should know about:

Ultraviolet radiation (UVR)

DOVONEX when used with ultraviolet radiation (UVR) may increase your risk of developing skin cancer caused by UVR. Your healthcare professional may recommend that you limit the time spent exposed to natural or artificial sunlight (e.g. sun tanning beds, sunlamps, etc.).

Skin:

Do not apply DOVONEX to your face as it may irritate the skin on your face or accidentally get in your eyes. Wash your hands after using DOVONEX to reduce the risk of irritating your face and eyes. Use the ointment carefully on body areas with skin folds, such as armpits or under breasts. If air cannot reach the skin under the fold, this area may become irritated if treated with DOVONEX.

Children

Children from 2 to 14 years of age should apply DOVONEX only when supervised by adults. Do not use DOVONEX in children under 2 years of age.

Pregnancy and breastfeeding:

If you are pregnant, able to get pregnant, think you are pregnant, or are breast feeding, there are specific risks you should discuss with your healthcare professional. Tell your healthcare professional if you are breast feeding, pregnant or become pregnant during your treatment. If your healthcare professional has allowed you to breast feed, do not apply DOVONEX to the breast area.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take DOVONEX:

- Your healthcare professional will tell you how much DOVONEX to use, or give to your child. Take DOVONEX exactly as instructed by the healthcare professional.
- Remove the cap. Check that the aluminium seal has not been broken before you use it for the first time. To break the seal, use the other end of the cap to pierce the seal.

How to apply DOVONEX:

- Gently rub DOVONEX on the areas of your skin affected by psoriasis. Wash your hands after using to prevent getting any on the face or in the eyes. You can wear your usual clothes and no special dressing or cover is needed.
- If you accidentally spread DOVONEX onto the surrounding healthy skin, wash it off right away.

Do not:

- DOVONEX may irritate your skin for a short while after you apply it, especially in skin folds (i.e., Arm pits and under breasts). Try not to scratch the area.
- Do not use DOVONEX on your face because it may irritate this more sensitive area of skin. If you accidentally get some on your face, wash it off right away.
- Do not use more than the maximum amount of DOVONEX in one week for your age group (see table below).

Usual dose:

Age (years)	Total Dovonex per week (g)
2-5	25
6 – 10	50
11 – 14	75
Adults (over 14)	100

DOVONEX used as the only treatment for psoriasis:

At the start of your treatment DOVONEX should be rubbed onto affected skin areas twice a day (morning and evening). Once your psoriasis improves your healthcare professional may reduce the dose to once a day.

DOVONEX used with other medicines for treatment of psoriasis:

Use each medicine once a day and at different times of the day (i.e., DOVONEX in the morning, the other medicine in the evening).

Overdose:

If you think you, or a person you are caring for, have used too much DOVONEX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use DOVONEX at the right time, use it as soon as you remember. Then go back to the regular dosing schedule.

What are possible side effects from using DOVONEX?

These are not all the possible side effects you may feel when using DOVONEX. If you experience any side effects not listed here, tell your healthcare professional.

The side effects of DOVONEX may include:

- Face and scalp irritation. This side effect is usually related to the accidental transfer of DOVONEX from other parts of your body
- Pain and skin discoloration at site of application
- Skin issues such as itching, burning, rash, hives, irritation and redness
- Small red bumps or white-headed pimples around hair follicles

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Common			
Worsening of psoriasis (symptoms of skin condition get worse): red patches of skin covered with thick, silvery scales, dry cracked skin that may bleed, itching, burning or soreness		✓	
Less Common			
Photosensitivity (sensitivity to sunlight): itchy, red skin when exposed to sunlight		✓	
Allergic reaction: itching, burning, rash, hives, irritation and redness			✓
Rare			
Hypercalcaemia (high blood calcium): tired, depression mental confusion, anorexia, nausea, vomiting, constipation, increased urination, heart rhythm problems.			✓

Hypercalciuria (high calcium in urine): Pain with urination, needing to go urgently or frequently, blood in urine, stomach pain.			✓
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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15-25°C). Use within 6 months of first opening the tube.

May be refrigerated. For easy application use at room temperature.

- Keep DOVONEX in a safe place out of the reach and sight of children.
- Keep DOVONEX away from your pets. Dogs like the taste of DOVONEX but the medicine can be fatal to dogs if eaten. If your dog eats DOVONEX contact a veterinarian immediately.
- Do not use DOVONEX past the expiry date marked on the bottom of the tube.

If you want more information about DOVONEX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.leo-pharma.ca, or by calling 1-800-263-4218].

This leaflet was prepared by LEO Pharma Inc.

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