

PART III: CONSUMER INFORMATION

PrDOVONEX® cream
PrDOVONEX® ointment
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.

ABOUT THIS MEDICATION

What the medication is used for:

- DOVONEX cream and ointment is used for the topical treatment of psoriasis on your body.
- DOVONEX may be used together with a moderate to very potent topical corticosteroid, cyclosporin A (oral) or acitretin (oral).
- DOVONEX 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) cream or ointment, or to components of the container.
- DOVONEX is not for use in your eyes.

What the medicinal ingredient is:

Calcipotriol

What the important nonmedicinal ingredients are:

Ointment: white soft paraffin, propylene glycol, liquid paraffin, polyoxyethylene-(2)-stearyl ether, purified water, disodium phosphate dehydrate, disodium edentate, DL- α -tocopherol.

Cream: white soft paraffin, cetostearyl alcohol, liquid paraffin, glycerol 85%, macrogol cetostearyl ether, disodium phosphate dehydrate, disodium edentate, chloroallylhexaminium (dowicil 200), purified water.

What dosage forms it comes in:

DOVONEX is available as an ointment (50 mcg/g), or a cream (50 mcg/g).

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. Use the cream or ointment carefully on body areas with skin folds. If air can not reach the skin under the fold, this area may become irritated if treated with DOVONEX.

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

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 is used (i.e., 100 g), there is the risk of developing high blood calcium levels.

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

- you have severe extensive psoriasis (the use of DOVONEX may not be recommended).
- 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 cream or ointment or to components of the container.

INTERACTIONS WITH THIS MEDICATION

DOVONEX has been used safely in combination with topical steroids. Except for steroids, there is no clinical trial experience on the interaction of DOVONEX with other topical drugs for psoriasis.

PROPER USE OF THIS MEDICATION

Usual dose:

At the start of your treatment DOVONEX should be rubbed onto affected skin 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 once a day will help keep your psoriasis under control.

Your doctor may prescribe using DOVONEX together with a steroid. Use each medicine once a day and at different times of the day (i.e., one in the morning, the other in the evening).

DOVONEX may also be used twice daily in combination with cyclosporin A or acitretin. There are no clinical studies in children of combination therapy with DOVONEX.

How to use the cream or ointment:

- 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.
- Gently rub DOVONEX on the areas of your skin affected by psoriasis. Wash your hands after using to prevent getting any on your face. 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.
- DOVONEX may irritate your skin for a short while after you apply it, especially in skin folds. Try not to scratch the area.
- DOVONEX is not recommended for use 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).

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

- If DOVONEX cream and ointment are used together then the total amount of DOVONEX should not be more than the maximum amount allowed for each age group in one week (see table above).
- If you use the cream or ointment in combination with DOVONEX scalp solution then the total amount of DOVONEX products (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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Face and scalp irritation is usually related to the accidental transfer of DOVONEX from other parts of your body. 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 | |
| Hypercalcaemia (high blood calcium) <ul style="list-style-type: none"> • very rare <i>Fatigue, depression mental confusion, anorexia, nausea, vomiting, constipation, increased urination and in some patients, cardiac arrhythmias</i> | ✓ | | ✓ |

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

HOW TO STORE IT

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

Ointment: Do not store above 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 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 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.

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
By email: 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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.leo-pharma.com/canada or by contacting the sponsor, LEO Pharma Inc. at: 1-800-668-7234.

© LEO Pharma A/S used under license by LEO Pharma Inc., Thornhill, L3T 7W8

**This leaflet was prepared by LEO Pharma Inc.
Last revised: September 6, 2018**

PART III: CONSUMER INFORMATION

^{PR}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.

ABOUT THIS MEDICATIONWhat 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 MEDICATIONUsual 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.

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

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
 By email: 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.

MORE INFORMATION

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

® LEO Pharma A/S used under license by LEO Pharma Inc., Thornhill, L3T 7W8

This leaflet was prepared by LEO Pharma Inc.
 Last revised: September 6, 2018