

Package leaflet: Information for the user
Dovonex[®] 50 micrograms/g cream
calcipotriol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Dovonex[®] cream will sometimes be called Dovonex.

What is in this leaflet

1. What Dovonex[®] is and what it is used for
2. What you need to know before you use Dovonex[®]
3. How to use Dovonex[®]
4. Possible side effects
5. How to store Dovonex[®]
6. Contents of the pack and other information

1. What Dovonex[®] is and what it is used for

Dovonex contains the active substance calcipotriol. Dovonex belongs to a group of medicines called anti-psoriatics. It is a type of vitamin D.

Vitamin D controls how the cells in your skin grow.

If the cells in your skin grow too much you may get psoriasis. Psoriasis is a condition where your skin develops raised red patches and silver coloured scaly patches. The scaly patches are dead cells that would normally fall off your skin without you noticing.

Dovonex works by reducing the amount of cells your skin makes. This means your symptoms will reduce too. You may begin to see an improvement in two to four weeks.

2. What you need to know before you use Dovonex[®]

Do not use Dovonex:

- If you are allergic (hypersensitive) to calcipotriol or any of the other ingredients of this medicine (listed in section 6).
- If you have been told by your doctor that you may have high or low levels of a substance called calcium in your body (calcium metabolism disorders).

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Dovonex:

- If you are already having ultraviolet (UV) light treatment.
- If you have guttate, erythrodermic, exfoliative or pustular psoriasis.
- If you have severe liver or kidney disease.

You may get too much calcium in your blood when you use this medicine. Please read section 4 of this leaflet so that you can spot any signs that this may be happening to you. Your doctor may need to change your dose.

You are not likely to get too much calcium in your blood if you use the dose prescribed for you. You can find the dose that you should use in section 3 of this leaflet. You are more likely to get too much calcium in your blood if you use more than the recommended dose each week.

Do not use Dovonex on your face, as it may irritate the skin on your face or accidentally get in your eyes.

Be careful when using Dovonex in skin folds such as armpits or under the breasts. You may be more likely to get skin side effects in these areas.

Your doctor may tell you to limit your exposure to natural or artificial sunlight, e.g. sunbathing and sun beds, while you are using this medicine.

Children

Do not use this medicine on children under 6 years old.

Other medicines and Dovonex:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines which you have bought without a prescription or herbal medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Dovonex contains:

- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
- Diazolidinyl urea. Diazolidinyl urea may cause local skin reactions (e.g. contact dermatitis).

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. How to use Dovonex®

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults

This medicine is normally used once or twice each day. It is normally used twice a day at the start of treatment and then once a day when the psoriasis seems to be clearing up. To remind

you to use your medicine, it may help to use it when you do another regular action, such as brushing your teeth.

Do not use more than 100 grams each week.

Use in children and adolescents

This medicine should be used twice each day. Use it as your doctor has told you to, but do not use more than these amounts each week.

Children over 12 years: Do not use more than 75 grams each week.

Children aged 6 to 12 years: Do not use more than 50 grams each week.

Children under 6 years: Not to be used by children in this age group.

Instructions for proper use

- This medicine should only be used on your skin
- Never put it on your face as it may cause irritation
- Do not swallow it
- Always wash your hands before using Dovonex
- Use only on your psoriasis and do not use on skin which does not have psoriasis
- Squeeze the cream onto a clean finger or directly onto the area affected by psoriasis
- Apply Dovonex to the affected area with your fingertips, and rub it in gently until the area affected by psoriasis is covered by a thin layer of cream
- Always wash your hands after using Dovonex. This will stop any medicine accidentally spreading to other parts of your body
- Do not mix Dovonex with any other medicines

Your doctor will tell you how much Dovonex cream to use and how long to use it for. Your dose will depend on how bad your psoriasis is.

If you use more Dovonex than you should

Tell your doctor straight away.

You may get too much calcium in your blood. Please read section 4 of this leaflet so you can spot any signs that this may be happening to you. Your doctor may tell you to stop using your medicine until the amount of calcium in your blood goes back to normal.

If you forget to use Dovonex

If you forget to use your medicine, use it as soon as you remember. Then next use your medicine at the usual time.

If you have any further questions about using this medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects to look out for:

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:

- **Your face, throat or eyes swell**
- **Your skin develops a severe rash**

You should tell your doctor straight away if you spot any of the following signs which may be due to too much calcium in your blood or urine which occurs rarely:

- **You need to pass water (urine) more often**
- **You feel thirsty or have lost your appetite**
- **You have a dry mouth or a metallic taste in your mouth**
- **You feel weak or have pain in your muscles or bones**
- **You have a headache or a pain in your stomach**
- **You feel or get sick or have constipation**

Other possible side effects:

Very common side effects (probably affect more than 1 in 10 people)

- Skin irritation

Common side effects (may affect up to 1 in 10 people)

- Worsening of your psoriasis
- Dermatitis
- Redness
- Rash
- Flaking skin
- Burning or stinging feeling
- Itching skin
- Pain where the medicine is applied

Uncommon side effects (may affect up to 1 in 100 people)

- Hypersensitivity (allergic reaction)
- Hypercalcaemia (too much calcium in your blood)
- Hypercalciuria (too much calcium in your urine)
- Increased sensitivity to sunlight
- Swelling of the skin due to fluid
- Seborrhoeic dermatitis (dermatitis where there are grease glands e.g face, centre of chest)
- Dry skin

Rare side effects (may affect up to 1 in 1000 people)

- Itchy raised rash (hives)
- Changes in your skin colour

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dovonex[®]

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date on the tube and carton (EXP). The expiry date refers to the last day of that month.
- Store below 25°C. Do not freeze.
- The tube should be discarded 6 months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dovonex contains

- The active substance is calcipotriol. Dovonex cream contains 50 micrograms of calcipotriol in each gram. The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, diazolidinyl urea, 2,4-dichlorobenzyl alcohol, disodium edetate, disodium phosphate dihydrate, glycerol 85%, liquid paraffin, white soft paraffin, all-rac- α -tocopherol, sodium hydroxide and purified water.

You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

What Dovonex looks like and contents of the pack

Dovonex cream is a white cream. It comes in aluminium tubes of 15 g, 30 g, 60 g, 100 g and 120 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder and Manufacturer:

LEO Laboratories Limited, Cashel Road, Dublin 12, Ireland.

For further information about this product, contact the local representative of the marketing authorisation holder:

Medical Division, LEO Laboratories Ltd, Dublin 12, Ireland

Telephone: +353 1 490 8924

Email: medical-info.ie@leo-pharma.com

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For information in large print, Braille or audio/CD, telephone +353 (0) 1 490 8924

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