

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dovonex[®] 50 micrograms/ml scalp solution

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[®] scalp solution 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.

Dovonex[®] is used to treat:

- Scalp psoriasis (psoriasis on the top of your head).

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 you use Dovonex[®]:

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

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.

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.

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

Children

This medicine is not recommended for use in children.

! 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 propylene glycol.

- Propylene glycol. may irritate your skin.

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

3. How to use Dovonex[®]

Always use Dovonex[®] exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for proper use

- This medicine should only be used on your scalp (the skin on the top of your head).
- Never put it on your face as it may cause irritation.
- Do not swallow it.
- Always wash your hands before using Dovonex[®].
- Use your medicine when your hair is dry. Part your hair before you use your medicine. This will help your medicine reach the skin on your head.
- Tilt your head back to stop any medicine running on to your face or in your eyes.
- Put the nozzle of the bottle close to your head. You can squeeze your medicine on to your head directly where the rash is. One or two drops will cover a small patch about the size of a postage stamp. Rub it in gently.
- Let your medicine dry naturally. It will not take long. Never dry it with a hairdryer or near a fire. Do not wash or dry your hair just after using your medicine. Leave your medicine on until next time you wash your hair. This will help it to work better.
- Always wash your hands after using Dovonex[®]. This will stop any medicine accidentally spreading to other parts of your body.
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- If you accidentally get any medicine in your eye, wash it out with water straight away. Then bathe your eye with an eyewash if possible. If your eye is sore go to your doctor.
- Keep your medicine away from your glasses or any plastic as it may damage them.
- Do not mix Dovonex[®] with any other medicines.

Your doctor will tell you how much Dovonex[®] scalp solution to use. Your dose will depend on how bad your psoriasis is.

You should use this medicine twice each day. Use it in the morning and in the evening. To remind you to use your medicine it may help to use it when you do another regular action, such as brushing your teeth.

Adults

- **Using only this medicine**
Do not use more than 60 millilitres (ml) each week
- **Using this medicine with other creams or ointments**
Please check with your doctor or pharmacist if you are using other medicines and you are not sure what they contain.

Remember your medicine contains the active ingredient called calcipotriol. You may use it

with other creams or ointments that also contain calcipotriol.

But you must use these medicines carefully together so you do not have too much in a week. Either:

Do not use more than 60 millilitres (ml) of Dovonex[®] scalp solution and 30 grams of calcipotriol cream or ointment each week.

or:

Do not use more than 30 millilitres (ml) of Dovonex[®] scalp solution and 60 grams of calcipotriol cream or ointment each week.

Ask your doctor or pharmacist if you are not sure how to use these medicines together.

Use in children

This medicine is not recommended for use in children.

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 taking 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 taking this medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Dovonex[®] 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 (may 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
- Dry skin
- 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
- Hives
- Seborrhoeic dermatitis (dermatitis where there are grease glands e.g face, centre of chest)

- Changes in your skin colour where the medicine is applied

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

- Swelling of the eyelids or face

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 which is stated on the bottle and carton (EXP). This expiry date refers to the last day of that month.
- Store below 25°C. Keep Dovonex® scalp solution away from fire or flames as it may catch fire. Do not throw away any medicines in wastewater or in household waste. Ask your pharmacist how to throw away any 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® scalp solution contains 50 micrograms of calcipotriol in each millilitre (ml).
- The other ingredients are hypromellose, isopropyl alcohol, levomenthol, sodium citrate, propylene glycol 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® scalp solution is a colourless, slightly thick liquid. Dovonex® scalp solution comes in plastic bottles of 60 ml and 120 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
LEO Laboratories Limited, Cashel Road, Dublin 12, Ireland.

Manufacturer:
LEO Pharma A/S, DK-2750 Ballerup, Denmark.

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

Medical Division, LEO Laboratories Ltd, Dublin 12, Ireland
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Email: medical-info.ie@leo-pharma.com

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