

Package leaflet: Information for the patient

Dovonex[®] Psoriasis 50 microgram/g ointment calcipotriol

What is in this leaflet

1. What Dovonex[®] Psoriasis is and what it is used for
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Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet Dovonex[®] Psoriasis 50 microgram/g ointment will be called Dovonex Psoriasis.
- **You must talk to your doctor if you do not see any improvement in your psoriasis after 4 weeks.**

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

Dovonex Psoriasis contains the active substance calcipotriol. This medicine 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.

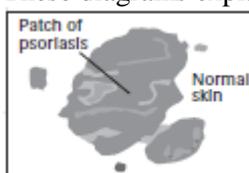
This medicine is used in adults to treat:

Mild or moderate plaque psoriasis (psoriasis vulgaris) which has been previously diagnosed by a doctor. Psoriasis is mild or moderate when it affects an area of skin no bigger than the skin surface on one of your arms.

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 Psoriasis works by reducing the amount of cells your skin makes. This means your skin symptoms will reduce too.

These diagrams explain how your skin may improve when you use this medicine.



Your skin before treatment.



After about two weeks you may see a change in your skin. The scaly or flaky patches usually clear up first. They will feel smoother.



The redness of the skin will start to clear up next. It may clear up in the centre first.

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

Do not use this medicine:

- If you are allergic to calcipotriol or any of the other ingredients of this medicine (listed in section 6)
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby
- If you have been told by a doctor that you have high or low levels of a substance called calcium in your body.

Warnings and precautions

You should see your doctor once a year for a routine check of your psoriasis.

Talk to your doctor before using this medicine:

- If your psoriasis is much worse or different to when your doctor last saw it
- If you have specific types of psoriasis covering large areas of the body (guttate or erythrodermic/exfoliative) or psoriasis with pus-filled bumps (pustular). Ask your doctor if you are unsure
- If your joints swell or are painful or if you have problems with your nails
- If you have liver or kidney problems
- If you are already having ultraviolet (UV) light treatment.

Stop using this medicine and talk to your doctor:

- If your psoriasis becomes worse at any time, or is no better after using the medicine every day for 4 weeks
- If you need to use more than 100 g of ointment per week.

You can use Dovonex Psoriasis for up to 12 weeks. If you feel your psoriasis has improved a lot or has completely cleared up, you may stop using this medicine at any time within 12 weeks. You may start to use this medicine again if your psoriasis comes back after clearing up.

You must see your doctor if you feel that your psoriasis has not cleared up by up to 50% after using this medicine for 12 weeks.

Excess calcium in the blood

This medicine can cause increases in calcium levels in the body so it is important that you do not use more than the recommended dose. You should apply Dovonex Psoriasis once a day and you must not use more than 100 g of ointment per week.

Signs of an increased blood calcium level can include:

- Passing water (urine) more frequently or in greater quantities than usual
- Increased thirst
- Dry or metallic taste in the mouth
- Stomach upsets (including pain, feeling sick, nausea, vomiting and constipation)
- Feeling weak or having pains in the muscles or bones
- Tiredness and confusion.

If you get any of these symptoms, stop using this medicine and tell your doctor straight away.

You are not likely to get too much calcium in your blood if you use this medicine as outlined in this leaflet or as your pharmacist has told you.

Do not use this medicine:

- on your face, as it may irritate the skin on your face or accidentally get in your eyes
- on your scalp, as in this area psoriasis is difficult to treat and special treatments may be needed
- on your genitals or in skin folds such as armpits or under the breasts, as you may be more likely to get skin side effects in these areas.

Do not cover your skin with any dressings or bandages when you have applied this medicine.

You should avoid sunbathing or using sunbeds while you are using this medicine.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents

Do not use this medicine on children and adolescents aged less than 18 years old as supervision by a doctor is needed in these age groups. Dovonex Psoriasis is only suitable for use in adults over 18 years old.

Other medicines and Dovonex Psoriasis

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

You should not use any other psoriasis treatment other than a moisturiser (emollient) while you are using this medicine.

Do not take any vitamin or mineral supplements, or any medicines, that contain calcium or vitamin D while using this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not use this medicine and talk to your doctor.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machines. Check with your pharmacist if you develop any side effects that may interfere with your ability to drive, operate machinery or take part in any other activity where they may put you or others at risk.

Dovonex Psoriasis contains propylene glycol 100 mg/g

Propylene glycol may cause skin irritation.

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

3. How to use Dovonex® Psoriasis

Always use this medicine exactly as described in this leaflet. You should check with your pharmacist if you are not sure.

How to apply Dovonex Psoriasis

This medicine is only for use on your skin. Do not swallow it. Do not put it inside your body.

Remove the cap. Check the seal is not broken before you first use the ointment. You will need to break the seal by using the point in the back of the cap.

Always wash your hands before using this medicine.

Apply the ointment to the skin which has the psoriasis. You can squeeze your medicine on to your skin directly, or you can squeeze it on to your finger first if you wish. Then rub it in gently to cover the psoriasis.

Always wash your hands after using Dovonex Psoriasis, unless you are treating your hands. This will stop any medicine accidentally spreading to other parts of your body. Do not worry if you accidentally get any ointment on your normal skin, but wash it off if it spreads too far.

Do not shower or bath immediately after applying the ointment.

You should try to keep your skin well moisturised, particularly after a bath or shower. If you use a moisturiser, wait for it to soak in before you apply your medicine.

How much Dovonex Psoriasis to use

Adults:

Apply Dovonex Psoriasis to the affected area once daily.

You can use this medicine for up to 12 weeks.

Do not use more than 100 grams each week.

You must see your doctor if you feel that your psoriasis has not improved by up to 50% after using this medicine for 12 weeks.

If you use more Dovonex Psoriasis than you should

Tell your doctor or pharmacist straight away and take this leaflet with you. If you use more of this medicine than you should, you may get too much calcium in your blood and your doctor may need to do a blood test to check for this. Your doctor may tell you to stop using this medicine until your calcium level goes back to normal.

If you forget to use Dovonex Psoriasis

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

Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, Dovonex Psoriasis 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:

- You have difficulty breathing
- Your face, including around your eyes, swells
- Your skin develops a severe rash, particularly if the skin is blistering or bleeding.

You should stop using this medicine and 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:

- 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 feel sick or have pain in your stomach (including nausea, vomiting and constipation)
- You feel tired, fatigued and confused.

Other possible side effects:

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

- Worsening of your psoriasis
- Skin inflammation
- Redness
- Flaking skin
- Burning or stinging feeling
- Skin irritation
- Itching skin
- Pain in the area where the medicine is used.

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

- Infection in a hair follicle
- Rash, including red, itchy, scaly rash. Blisters may form. These may weep or become crusty
- Dry skin
- Changes in skin colour where the medicine is used.

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

- Allergic reaction
- Too much calcium in the blood
- Temporary increased sensitivity to sunlight
- Skin swelling or puffiness
- Itchy raised rash (hives)
- Skin conditions where there are oily glands. For example; on the face, centre of chest, or conditions such as dandruff
- Too much calcium in the urine.

Not known (frequency cannot be estimated from the available data)

- Swelling or puffiness around the eyes or face.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, website: www.hpra.ie

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

5. How to store Dovonex® Psoriasis

- 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 is the last day of that month.
- The tube should be discarded 6 months after first opening. Write the date you first opened the tube in the space provided on the carton.
- Do not store above 25°C.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. Contents of the pack and other information

What Dovonex Psoriasis contains

- The active substance is calcipotriol. Dovonex Psoriasis contains 50 micrograms of calcipotriol in each gram of ointment.
- The other ingredients are disodium edetate, disodium phosphate dihydrate, all-*rac*- α -tocopherol, liquid paraffin, macrogol-(2)-stearyl ether, propylene glycol, purified water and white soft paraffin.

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

What Dovonex Psoriasis looks like and contents of the pack

This medicine is an off-white to yellowish-white translucent ointment. It comes in aluminium tubes of 60 grams.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in April 2020.

For information in large print, Braille or audio/CD, telephone +353 (0)1 4908924

®Registered Trade Mark

FURTHER HELPFUL INFORMATION

People with psoriasis should see their doctor once a year for a regular check-up of their skin, their treatment and their general health. This is because psoriasis can affect other parts of the body as well as the skin. This is more likely if psoriasis is severe.

Moisturisers (emollients) are useful in treating psoriasis. Moisturisers can reduce skin dryness and itching. They can also reduce skin scaling and soften hard cracked areas, which may help treatments such as Dovonex Psoriasis to get into the skin.

You should use moisturisers instead of soap when washing or having a bath. Feel free to moisturise generously as often as you like, since this will help your skin symptoms.

It is a good idea to use a moisturiser before you treat your psoriasis, but allow about 30 minutes between moisturising and using Dovonex Psoriasis.

Please remember to keep Dovonex Psoriasis out of the reach of pets. If you suspect that your pet has

eaten Dovonex Psoriasis or chewed the tube, please contact your vet as soon as possible as it may be harmful to your pet.