

Daivonex® cream

Calcipotriol (*Kal-sippo-try-all*)

Consumer Medicine Information

Please read this leaflet carefully before you start your treatment.

Keep this leaflet.

You may want to read it again.

What is in this leaflet?

This leaflet answers some common questions about using Daivonex®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Daivonex® against the benefits it is expected to have for you.

If you have any concerns about using Daivonex®, talk to your doctor or pharmacist.

What Daivonex® is used for

Daivonex® is an anti-psoriasis medicine. Daivonex® contains calcipotriol (related to Vitamin D). Daivonex® does **not** contain steroids.

Daivonex® is used only on skin affected by psoriasis. Psoriasis is a skin disorder in which skin cells are overactive. The calcipotriol in Daivonex® treats the overactive skin cells.

Daivonex® is used in the commonest type of psoriasis, where "plaques" form on the skin. Plaques are raised, rough, reddened areas covered with fine, dry silvery scales.

Daivonex® cream is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

This medicine is not addictive.

Before you use Daivonex®

When you must not use Daivonex®

Do not use Daivonex® if you have an allergy to:

- any medicine containing calcipotriol
- any of the ingredients listed at the end of this leaflet (see Product description).

Some of the symptoms of an allergic reaction include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or "hives" on the skin.

Do not use Daivonex® for severe widespread psoriasis, or the types of psoriasis known as guttate, generalised pustular or erythrodermic exfoliative psoriasis.

Your doctor will identify these conditions for you.

Do not use Daivonex® if you

- have high blood calcium levels.
- are taking calcium, vitamin D supplements or vitamin D-like medicines, for example calcitriol.

Do not use Daivonex®

- **after the expiry date printed on the pack OR**
- **if the packaging is torn, doesn't look quite right or shows signs of tampering.**

If the Daivonex® packaging is damaged or it is past the expiry date, return it to your pharmacist for disposal.

Do not breast-feed if you are using Daivonex® on your breasts.

If you are not sure whether you should start using Daivonex®, talk to your doctor.

Do not use Daivonex® cream in children.

The safety and effectiveness of Daivonex® cream in children under 18 has not been established.

Do not use Daivonex® cream

if you are having or using other treatments for psoriasis unless otherwise advised by your doctor.

Before you start to use it

Tell your doctor if you have a known allergy to Daivonex® or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you

- have kidney or liver problems
- are suffering from any other illness.

Tell your doctor if you

- **are pregnant**
- **are breast-feeding**
- **intend to breast-feed.**

If you have not told your doctor about any of the above, tell him/her before you start using this medicine.

Other medicines

Tell your doctor or pharmacist if you are on any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines you should be careful with or avoid whilst using Daivonex®.

How to use Daivonex®

Follow carefully all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much Daivonex® to use

In one week do not use more than 100 g (no more than three 30 g tubes of Daivonex® cream).

Using combinations of Daivonex® and Daivobet® preparations

You may need to use Daivonex® cream on your body and other products containing calcipotriol (e.g. Daivobet® gel or Daivobet® ointment) on other parts of your body or at different times.

In one week do not use more than

100g (no more than three 30g tubes or bottles) of Daivonex® and Daivobet® **NOTE:** If you use more than the recommended amount, the levels of calcium in your body may rise, and this can have serious effects.

How to use Daivonex®

NOTE: unlike certain other skin preparations which you use sparingly, use Daivonex® as follows:

- Apply Daivonex® cream to the psoriasis plaques only. Form a visible coating. If you accidentally get some of the cream on normal skin, wash it off.

- **DO NOT** use Daivonex® cream
 - in skin folds,
 - on the genitalia,
 - on the scalp or
 - on the face.

Wash your hands thoroughly after applying it on any part of your body, unless your hands are being treated.

Take care not to get Daivonex® in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.

If any skin irritation develops,

wash off the Daivonex®.

Do not use Daivonex® on the face.

An itchy red rash may develop.

Do not use Daivonex®

under occlusive dressings (eg. a bandage). The treated area does not need to have a special covering. You may wear your usual clothes.

When to use Daivonex® preparations

Apply Daivonex® twice a day (morning and night).

How long to use it

Continue to use Daivonex® for as long as your doctor tells you.

If you are using Daivonex® for longer than 3 months your doctor may do blood tests to check your calcium levels and kidney function.

Your doctor may decide to stop Daivonex® treatment once your psoriasis has improved.

If you forget to use it

If you forget to use Daivonex®, use it as soon as you remember. Then go on as before.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

If you use too much or use it other than directed. (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 03 474 7000 in New Zealand) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much or swallowed some of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Daivonex®

Things you must do

While you are using Daivonex®, protect the treated skin areas from sunlight and Ultra Violet (UV) rays, for example, by wearing protective clothing. This is particularly important if your job or lifestyle means you spend much time outdoors.

If you are going to start any new medicine, tell your doctor and pharmacist that you are using Daivonex®.

If you become pregnant while using Daivonex®, tell your doctor immediately.

Keep all appointments with your doctor so that your progress can be checked.

Your doctor may do some blood tests from time to time.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use Daivonex® with other treatments for psoriasis unless prescribed by your doctor.

Do not use more than the recommended weekly dose (see How to use Daivonex®).

Side effects

As with all medicines, Daivonex® can cause some side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist:

- **if you have any unpleasant effects while you are using Daivonex®**
or
- **if you notice any of the following and they worry you:**
 - skin irritation (including rashes or peeling)
 - a rash on your face
 - a change in the colour of your skin
 - your skin is more sensitive to light.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Daivonex®

Keep Daivonex® in the box until required.

Storage

Keep your Daivonex® in a cool dry place where the temperature stays below 25°C.

However, do not keep it in the refrigerator as it will not spread easily.

Do not store Daivonex® or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Daivonex® where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Daivonex® or the expiry date has passed, ask your pharmacist what to do with any Daivonex® that is left over.

Product description

What it looks like

Daivonex® cream is a soft white cream.

Ingredients

Daivonex® cream contains the active ingredient calcipotriol (50 microgram/gram). It also contains

- disodium edetate
- quaternium-15
- sodium phosphate - dibasic dihydrate
- cetomacrogol 1000
- glycerol
- liquid paraffin
- cetostearyl alcohol
- soft white paraffin
- purified water.

Daivonex® does not contain lactose, sucrose, gluten, tartrazine or any other azo products.

The Australian Registration Number (AUST R) is 57354.

This is not all the information available on Daivonex®. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

LEO Pharma Pty Ltd,

Level 3, Tower 1,
25 Montpelier Road,
Bowen Hills, QLD 4006,
AUSTRALIA

Web: www.leo-pharma.com.au
Australia Toll free no: 1800 991 778

Daivonex® cream is manufactured by: LEO Laboratories Ltd (LEO Pharma), IRELAND

Daivonex, LEO and LEO/lion device are registered trademarks of LEO Pharma A/S, Denmark.

This leaflet was prepared in April 2002 and last modified in July 2012.

LPS-12-031