Consumer Medicine Information

Daivonex® ointment

Calcipotriol (Kal-sippo-try-all)

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[®] ointment. 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® ointment against the benefits it is expected to have for you.

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

What Daivonex® ointment is used for

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

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

Daivonex[®] ointment is used in the commonest type of psoriasis, where "plaques" form in the skin. Plaques are raised, rough, reddened areas covered with fine, dry silvery scales. Plaques are usually a centimetre or two across.

Daivonex® ointment 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® ointment

When you must not use Daivonex® ointment

Do not use Daivonex® ointment 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® ointment 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® ointment 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® ointment

- 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[®] ointment 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® ointment on your breasts.

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

Daivonex[®] **ointment** may be used in children (see **How to use Daivonex**[®] **ointment**).

Daivonex® **ointment** may be used with some other treatments for psoriasis. Talk to your doctor to find out if this applies to you.

Before you start to use it

Tell your doctor if you have a known allergy to Daivonex® ointment 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® ointment.

How to use Daivonex® ointment

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® ointment to use

Children:

- over 12 years old
 - Do not use more than 75 g in one week.
- 6 12 years old
 - Do not use more than 50 g in one week.
- under 6 years old
 - Follow your doctor's instructions.

Adults:

- Do not use more than 100 g in one week. For example, no more than 1 tube of 100 g or 3 tubes of 30 g.

If you are using other calcipotriol containing products (e.g. Daivobet® gel or Daivobet® ointment) on your psoriasis, then the **total** amount of calcipotriol products must not exceed 15 grams per day or 100 grams per week.

How to use Daivonex® ointment

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

- Apply Daivonex[®] ointment to the psoriasis plaques only. Form a visible coating. If you accidentally get some of the ointment on normal skin, wash it off.
- DO NOT use Daivonex[®] ointment
 - in skin folds,
 - on the genitalia,
 - on the scalp or
 - on the face.
- If any accidentally gets on your face, wash it off immediately.

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® ointment in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.

Avoid getting Daivonex® ointment on your face accidentally.

If any skin irritation develops, wash off the Daivonex® ointment.

Do not use Daivonex® ointment on the face. An itchy red rash may develop.

Do not use Daivonex® **ointment** under occlusive dressings (e.g. a bandage). The treated area does not need to have a special covering. You may wear your usual clothes.

When to use Daivonex® ointment

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

How long to use it

Children:

Do not use Daiyonex® ointment for more than 8 weeks.

Adults:

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

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

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

If you forget to use it

If you forget to use Daivonex® ointment, 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 (0800 764 766 / 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® ointment

Things you must do

While you are using Daivonex® ointment, 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 out-of-doors. [An exception is if your doctor has advised combination treatment with Daivonex® ointment and UV therapy.]

If you are going to start any new medicine, tell your doctor and pharmacist that you are using Daiyonex[®] ointment.

If you become pregnant while using Daivonex® ointment, 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.

Your doctor will tell you if you can use **Daivonex**® **ointment** with other psoriasis treatments.

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

Side effects

As with all medicines, Daivonex® ointment 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® ointment 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® ointment

Keep Daivonex® ointment in the box until required.

Storage

Keep your Daivonex® ointment in a cool dry place where the temperature stays below 25°C. However, do not keep Daivonex® ointment in the refrigerator as the ointment will not spread easily.

Do not store Daivonex® ointment 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® **ointment 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[®] ointment or the expiry date has passed, ask your pharmacist what to do with any Daivonex[®] ointment that is left over.

Discard Daivonex[®] Ointment 6 months after opening.

Product description

What it looks like

Daivonex® **ointment** is a white to yellowish ointment.

Ingredients

Daivonex® **ointment** contains the active ingredient calcipotriol (50 microgram/g). It also contains:

- dl-α-tocopherol
- disodium edetate,
- sodium phosphate dibasic dihydrate
- purified water
- liquid paraffin
- steareth-2
- propylene glycol
- soft white paraffin.

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

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

Supplier

Daivonex® ointment is supplied in pack sizes 100 g and 120 g in New Zealand by:

LEO Pharma Ltd Auckland, New Zealand Toll Free No. 0800 497 456

® LEO, LEO/Lion device and Daivonex are registered trademarks of LEO Pharma A/S

This leaflet was prepared in June 2020.