

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Daivonex[®] Ointment?

Daivonex[®] Ointment contains the active ingredient Calcipotriol monohydrate. Daivonex[®] Ointment is used as an anti-psoriasis medicine applied to skin affected by psoriasis

For more information, see Section [1. Why am I using Daivonex[®] Ointment?](#) in the full CMI.

2. What should I know before I use Daivonex[®] Ointment?

Do not use if you have ever had an allergic reaction to Daivonex[®] Ointment or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Daivonex[®] Ointment?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Daivonex[®] Ointment and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I 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.

More instructions can be found in Section [4. How do I use Daivonex[®] ointment?](#) in the full CMI.

5. What should I know while using Daivonex[®] Ointment?

Things you should do	<ul style="list-style-type: none">• 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. [Discuss best sun protection and application times 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 Daivonex 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 should not do	<ul style="list-style-type: none">• 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).
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Daivonex[®] Ointment affect you.
Looking after your medicine	<ul style="list-style-type: none">• Keep Daivonex[®] ointment in the box until required.• 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.

For more information, see Section [5. What should I know while using Daivonex[®] ointment?](#) in the full CMI.

6. Are there any 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Daivonex[®] Ointment

Active ingredient(s): *Calcipotriol Monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Daivonex[®] Ointment. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Daivonex[®] Ointment.**

Where to find information in this leaflet:

- [1. Why am I using Daivonex[®] Ointment?](#)
- [2. What should I know before I use Daivonex[®] ointment?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Daivonex[®] Ointment ?](#)
- [5. What should I know while using Daivonex[®] Ointment?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Daivonex[®] Ointment?

Daivonex[®] Ointment contains the active ingredient Calcipotriol monohydrate.

Daivonex[®] ointment contains calcipotriol (related to Vitamin D). Daivonex[®] ointment is an anti-psoriasis medicine. 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.

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.

2. What should I know before I use Daivonex[®] ointment?

Warnings

Do not use Daivonex[®] Ointment if:

- If you have allergy to any medicine containing calcipotriol or to any of the ingredients listed at the end in product details.

- 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 take this medicine
 - if you have high blood calcium levels.
 - are taking calcium, vitamin D supplements or vitamin D-like medicines, for example calcitriol unless advised by your doctor and levels are closely monitored..
- 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.
- 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.

Check with your doctor if you:

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking 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.**

4. How do I use Daivonex[®] ointment?

How to use it

- 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 once or twice a day (morning and night).

How much to take / 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.

When to take / use Daivonex[®] Ointment

- Apply Daivonex[®] ointment once or twice a day (morning and night). In the beginning of treatment twice a day is usually preferred.

How long to use Daivonex[®] ointment

- **Children:**
Do not use Daivonex[®] 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 Daivonex[®] ointment

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 Daivonex[®] ointment

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this if you think that you or anyone else may have used too much or swallowed some of this medicine, even if there are no signs of discomfort or poisoning.

5. What should I know while using Daivonex[®] ointment?

Things you should 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. [Discuss best sun protection and application times 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 Daivonex[®] ointment.

Call your doctor straight away if you:

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 should not do

- Do not give Daivonex[®] Ointment 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).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Daivonex[®] Ointment affects you.

Daivonex[®] Ointment generally do not cause any problems with your ability to drive a car or operate machinery.

Looking after your medicine

- 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.

When to discard your medicine

If your doctor tells you to stop taking Daivonex[®] Ointment or the expiry date has passed, ask your pharmacist what to do with any Daivonex[®] Ointment that are left over.

Discard Daivonex[®] Ointment 6 months after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date.

6. Are there any 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Daivonex[®] Ointment contains

Active ingredient (main ingredient)	Calcipotriol(50 microgram/g)
Other ingredients (inactive ingredients)	- dl- α -tocopherol - disodium edetate, - sodium phosphate - dibasic dihydrate - purified water - liquid paraffin - steareth-2 - propylene glycol - soft white paraffin

Do not take this medicine if you are allergic to any of these ingredients.

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

What Daivonex[®] Ointment looks like

Daivonex[®] Ointment is a white to yellowish ointment.

The Australian Registration Number for Daivonex[®] Ointment is AUST R 46683.

Who distributes Daivonex[®] Ointment

Daivonex[®] Ointment is supplied in Australia by:

LEO Pharma Pty Ltd

Brisbane, QLD Australia

Toll free no: 1800 991 778

Web: www.leo-pharma.com.au

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