

DAIVONEX(R) ointment, cream and scalp solution

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(R). 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(R) against the benefits it is expected to have for you.

If you have any concerns about using DAIVONEX(R), talk to your doctor or pharmacist.

What DAIVONEX(R) is used for

DAIVONEX(R) is an anti-psoriasis medicine. DAIVONEX(R) contains calcipotriol (related to Vitamin D). DAIVONEX(R) does not contain steroids.

DAIVONEX(R) is used only on skin affected by psoriasis. Psoriasis is a skin disorder in which skin cells are overactive. The calcipotriol in DAIVONEX(R) treats the overactive skin cells.

DAIVONEX(R) 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(R) preparations are available as ointment, cream and scalp solution.

DAIVONEX(R) preparations are 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(R)

When you must not use DAIVONEX(R) (All Preparations)

Do not use DAIVONEX(R) 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(R) 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(R) 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(R)

- * **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(R) 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(R) on your breasts.

If you are not sure whether you should start using DAIVONEX(R), talk to your doctor.

When you must not use DAIVONEX(R) Cream or Scalp Solution

Do not use DAIVONEX(R) cream or scalp solution in children.

Safety and effectiveness of these forms of DAIVONEX(R) in children have not been established.

DAIVONEX(R) ointment may be used in children (see How to use DAIVONEX(R)).

Do not use DAIVONEX(R) cream or scalp solution if you are having other treatments for psoriasis.

DAIVONEX(R) 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(R) 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(R).

How to use DAIVONEX(R)

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 of each DAIVONEX(R) preparation to use

Children:

DAIVONEX(R) ointment only

- * **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:

- * **DAIVONEX(R) cream and ointment:**
 - Do not use more than 100 g in one week.For example, no more than
 - * 3 tubes of 30 gor
 - * 1 tube of 100 g.

Adults:

- * **DAIVONEX(R) scalp solution:**
 - Do not use more than 60 mL in one week.For example, no more than
 - * 1 bottle containing 60 mLor
 - * 2 bottles containing 30 mL.

Adults:

- * **Using combinations of DAIVONEX(R) preparations**
IMPORTANT: You may need to use a combination of

DAIVONEX(R) preparations to treat your psoriasis. For example, you may use scalp solution on your head and ointment or cream on other parts of your body.

- **In one week do not use more than**

- * 60 mL of DAIVONEX(R) scalp solution plus one 30 g tube of DAIVONEX(R) cream or ointment

or

- * 30 mL of DAIVONEX(R) scalp solution plus two 30 g tubes of DAIVONEX(R) cream or ointment.

- **In one week do not use more than**

- * one 30 g tube of DAIVONEX(R) cream and two 30 g tubes of DAIVONEX(R) ointment

or

- * two 30 g tubes of DAIVONEX(R) cream and one 30 g tube of DAIVONEX(R) ointment.

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(R) preparations

NOTE: unlike certain other skin preparations which you use sparingly, use DAIVONEX(R) as follows:

- * **DAIVONEX(R) cream and ointment:**
 - Apply DAIVONEX(R) cream or ointment to the psoriasis plaques only. Form a visible coating. If you accidentally get some of the cream or ointment on normal skin, wash it off.
 - DO NOT use DAIVONEX(R) cream or ointment

- * in skin folds,
- * on the genitalia,
- * on the scalp or
- * on the face.

*** DAIVONEX(R) scalp solution:**

- Use DAIVONEX(R) scalp solution ONLY on the scalp.
- Apply DAIVONEX(R) scalp solution, drop by drop, only to the areas of your scalp that have psoriasis.
- 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(R) in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.

Avoid getting DAIVONEX(R) on your face accidentally.

If any skin irritation develops, wash off the DAIVONEX(R) preparation.

Do not use DAIVONEX(R) on the face.

An itchy red rash may develop.

Do not use DAIVONEX(R) 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(R) preparations

Apply DAIVONEX(R) twice a day (morning and night).

How long to use it

*** Children:**

Do not use DAIVONEX(R) ointment for more than 8 weeks.

*** Adults:**

Continue to use DAIVONEX(R) for as long as your doctor tells you.

If you are using DAIVONEX(R) 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(R) treatment once your psoriasis has improved.

If you forget to use it

If you forget to use DAIVONEX(R), 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(R)

Things you must do

While you are using DAIVONEX(R), 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(R) ointment and UV therapy].

If you are going to start any new medicine, tell your doctor and pharmacist that you are using DAIVONEX(R).

If you become pregnant while using DAIVONEX(R), 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(R) cream or scalp solution with other treatments for psoriasis.

Your doctor will tell you if you can use DAIVONEX(R) ointment with other psoriasis treatments.

Do not use more than the recommended weekly dose (see How to use DAIVONEX(R)).

Side effects

As with all medicines, DAIVONEX(R) 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(R)**

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(R)

Keep DAIVONEX(R) in the box until required.

Storage

Keep your DAIVONEX(R) ointment or cream or scalp solution in a cool dry place where the temperature stays below 25 degrees C.

However, do not keep DAIVONEX(R) cream or ointment in the refrigerator as the cream or ointment will not spread easily.

Also, keep your DAIVONEX(R) scalp solution away from fire or flames because it may catch fire.

Do not store DAIVONEX(R) 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(R) 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(R) or the expiry date has passed, ask your pharmacist what to do with any DAIVONEX(R) that is left over.

Product description

What it looks like

DAIVONEX(R) ointment is a white to yellowish ointment.

DAIVONEX(R) cream is a soft white cream.

DAIVONEX(R) scalp solution is a colourless, non-runny solution.

Ingredients

DAIVONEX(R) ointment contains the active ingredient calcipotriol (50 microgram/g). It also contains

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

DAIVONEX(R) cream contains the active ingredient calcipotriol (50 microgram/g). It also contains

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

DAIVONEX(R) scalp solution contains the active ingredient calcipotriol (50 microgram/mL).

It also contains

- * menthol
- * hydroxypropylcellulose
- * sodium citrate
- * propylene glycol
- * isopropyl alcohol
- * purified water.

DAIVONEX(R) does not contain lactose, sucrose, gluten, tartrazine or any other azo products.

The Australian Registration Numbers are

DAIVONEX(R) ointment

AUST R 46683

DAIVONEX(R) cream

AUST R 57354

DAIVONEX(R) scalp solution

AUST R 63268

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

Supplier

DAIVONEX(R) is supplied in Australia by:

CSL Limited
 ABN 99 051 588 348
 45 Poplar Rd
 Parkville 3052 VIC
 AUSTRALIA

and in New Zealand by:

CSL (New Zealand) Limited
 666 Great South Road
 Central Park
 Auckland
 NEW ZEALAND
 Telephone: 09 579 8105

DAIVONEX(R) is manufactured by:

Leo Pharmaceutical Products Ltd A/S
 Ballerup
 DENMARK
 Proprietor of the registered trademark LEO, LION Device and DAIVONEX.

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