DAIVONEX® CREAM

Calcipotriol (50 mcg/g)

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What Daivonex® Cream is used for

Daivonex[®] contains calcipotriol (type of Vitamin D). Daivonex[®] does not contain steroids.

Daivonex® Cream is used for psoriasis vulgaris. Psoriasis is a skin disorder in which skin cells are being produced too quickly.

This causes "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.

How Daivonex® Cream works

Daivonex[®] Cream works by reducing the amount of cells your skin makes. This means your skin symptoms will reduce too.

Before you use Daivonex® Cream

- When you must not use it

Do not use *Daivonex*[®] *Cream* if you have an allergy to:

- any medicine containing calcipotriol
- any of the ingredients listed at the end of this leaflet (see section: 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® Cream if you

■ have high blood calcium levels

Pregnancy and lactation

Do not take *Daivonex*[®] *Cream* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Daivonex*[®] *Cream* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

The safety of *Daivonex*® *Cream* in human pregnancy has not been established.

- Before you start to use it

Tell your doctor if you

are suffering from any other illness.

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

- 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*® *Cream*.

Do not use *Daivonex Cream* with Salicylic acid. Concurrent treatment with topical preparations containing salicylic acid should be avoided as salicylic acid may inactivate calcipotirol.

How to use Daivonex® Cream

Wash your hands thoroughly after applying it on any part of your body, unless your hands are being treated. Apply sparingly to the affected skin lesions.

Do not use *Daivonex*® *Cream* on the face.

- How much to use

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

- When to use it

Apply Daivonex® Cream twice a day

- How long to use it

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

- If you forget to use it

If you forget to use *Daivonex*[®], use it as soon as you remember. Then continue 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 (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Excessive use (more than 100g Daivonex® Cream weekly) may cause elevated calcium in the blood, which rapidly subsides when the treatment is discontinued.

While you are using it

- Things you must do

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

If you become pregnant while using *Daivonex*® *Cream*, 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*[®] *Cream* with other treatments for psoriasis unless prescribed by your doctor.

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

- Things to be careful of

This medicine is not addictive.

Side effects

As with all medicines, *Daivonex*® *Cream* 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® Cream

or

if you notice any of the following and they worry you:
 -transient local irritation
 -facial skin inflammation

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 0378835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Daivonex® Cream

- Storage
 - Keep out of the reach and sight of children.
 - Store at controlled room temperature (15°C 25°C)
 - 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.
 - Do not use *Daivonex*® *Cream* after the expiry date printed on the pack or if the packaging is torn, does not look quite right or shows signs of tampering.

- Disposal

If your doctor tells you to stop using $Daivonex^{@}$ Cream or the expiry date has passed, ask your pharmacist what to do with any $Daivonex^{@}$ Cream that is left over.

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

Product Description

- What it looks like

Daivonex® cream is a soft white cream.

- Ingredients

 Active ingredient Calcipotriol (50 microgram/gram)

- Inactive ingredients
 - Cetomacrogol
 - Cetostearyl alkohol
 - Chloroallylhexaminium chloride
 - Disodium edetate
 - Disodium phosphate dihydrate
 - Glycerol
 - Liquid parafin
 - White Soft Parafin
 - Purified water

- MAL number: MAL19961672AZ

Manufacturer

LEO Pharmaceutical Products A/S Limited Industriparken 55 DK-2750 Ballerup, Denmark

Product Registration Holder

DKSH Malaysia Sdn Bhd B-11-01, The Ascent, Paradigm, No.1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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