

DAIVONEX[®] OINTMENT

Calcipotriol (50 micrograms/ml)

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What *Daivonex[®] Ointment* is used for

Daivonex[®] Ointment is used to treat psoriasis vulgaris.

Daivonex[®] Ointment belongs to a group of medicines called anti-psoriatics. It is a topical formulation of the Vitamin D derivative, calcipotriol, which controls how the cells in your skin grow.

If the cells in your skin grow too much you may get psoriasis. Psoriasis is the condition where your skin develops red patches and silver coloured scaly patches. The scaly patches are dead cells that would normally fall off your skin without you noticing.

How *Daivonex[®] Ointment* works

Daivonex[®] Ointment works by reducing the amount of cells your skin makes. Thus, it normalizes abnormal skin growth.

Gradually, you may see a change in your skin. The scaly or flaky patches usually clear up first. They will feel smoother.

The redness of the skin will start to clear up next. It may clear up in the centre first.

Before you use *Daivonex[®] Ointment*

- *When you must not use it*

Do not use *Daivonex[®] Ointment*

- If you are allergic (hypersensitive) to calcipotriol or any of the other ingredients of *Daivonex[®] Ointment*.
- If you have been told that you have high levels of a substance called calcium in your body (calcium metabolism disorders).

Pregnancy and breast-feeding

Please ask your doctor or pharmacist for advice before using *Daivonex[®] Ointment*:

- If you are pregnant, or think you are pregnant.
- If you are breast-feeding.

- The safety of *Daivonex[®] Ointment* in human pregnancy has not been established. Tell your doctor if you become pregnant while using this medicine. If your doctor has agreed that you can breast-feed, do not apply *Daivonex[®] Ointment* to the breast area.

- *Before you start to use it*

Take special care with *Daivonex[®] Ointment*

Before using this medicine, tell your doctor:

- If you are already having ultraviolet (UV) light treatment. You must discuss with your doctor about having light treatment and using *Daivonex[®] Ointment* at the same time.

Children

The safety and efficacy of *Daivonex[®] Ointment* in the treatment of children have not yet been established.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Daivonex[®] Ointment is a ready-for-use preparation and should not be mixed with other ingredients of preparations.

Concurrent treatment with topical preparations containing salicylic acid

should be avoided as it inactivates calcipotriol.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Any other medicines to treat psoriasis.

How to use *Daivonex[®] Ointment*

- *How to put on*

Always use *Daivonex[®] Ointment* exactly as your doctor has told you.

Instruction for proper use

- This medicine is only for using on your skin. Do not swallow it or put it inside your body.
- Never put this medicine on your face as it may cause irritation.
- Remove the cap and check that the seal in the tube is not broken before you first use the ointment.
- If you have a 30 gram or 100 gram tube, you will need to break the seal, by using the point in the back of the cap.
- Put your medicine on the skin which has psoriasis.
- Always wash your hands after using *Daivonex[®] Ointment*.

- *How much to use*

- Your doctor will tell you how much *Daivonex[®] Ointment* to use. For best results, use *Daivonex[®] Ointment* twice daily.
- If you use it twice a day, use it in the morning and in the evening. To remind you to use your medicine it may help to use it when you do another regular action, such as brushing your teeth.
- Your dose will depend on how bad your psoriasis is and your doctor will prescribe the dose that is right for you.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

- Follow the advice of your doctor.
- Do not use more than 100 grams each week.

- If you forget to use it

- Use it as soon as you remember. Then next use your medicine at the usual time.
- If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

- If you use too much (overdose)

- Tell your doctor straight away.
- You may get too much calcium in your blood.

You should tell your doctor straight away if you spot any of the following signs which may be due to too much calcium in your blood:

- You need to pass water (urine) more often
- You feel thirsty
- You have a dry mouth or a metallic taste in your mouth
- You feel weak or have pain in your muscles or bones
- You feel sick or have constipation

While you are using it

- Things you must do

- Always use *Daivonex*[®] Ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Please tell your doctor or pharmacist treating you that you are using *Daivonex*[®] Ointment

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give *Daivonex*[®] Ointment to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

- Your doctor may tell you to limit your exposure to natural or artificial sunlight while you are using this medicine.

You are not likely to get too much calcium in your blood if you use the dose prescribed for you. You can find the dose that you should use in section “*How much to use*” of this leaflet. You are more likely to get too much calcium in your blood if you use more than the recommended dose each week.

Side effects

Like all medicines, *Daivonex*[®] Ointment can cause side effects, although not everybody gets them.

Important side effects to look out for:

You must get urgent medical help if you have the following symptoms. You may be having an allergic reaction:

- You have difficulty breathing
- Your face including around your eyes swell
- Your skin develops a severe rash

Minor adverse effects such as temporary local irritation and, very rarely, facial irritation may occur.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-

78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of *Daivonex*[®] Ointment

- Storage

- Keep out of the reach and sight of children.
- Do not use after the expiry date on the carton. The expiry date refers to the last day of that month.
- Do not store the product above 30°C.

- Disposal

- Medicines should not be thrown away via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Daivonex[®] Ointment is an off-white to yellowish white translucent ointment. *Daivonex*[®] Ointment comes in tubes of 30 grams and 100 grams. Not all pack sizes are marketed in the country.

- Ingredients

- Active ingredient is Calcipotriol *Daivonex*[®] Ointment containing 50 micrograms of calcipotriol in each gram of ointment.
- Inactive ingredients are disodium edetate, disodium phosphate dihydrate, DL- α tocopherol, liquid paraffin, macrogol stearyl ether, propylene glycol, purified water and white soft paraffin.

- MAL number:

MAL19921382A

Manufacturer

LEO Laboratories Ltd
285 Cashel Road, Crumlin
Dublin 12, Ireland

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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