

**Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only

**Daivobet® ointment**

**Active ingredients:**  
Calcipotriol 50 mcg/g (as hydrate)  
Betamethasone 0.5 mg/g (as dipropionate)

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

**Read this entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.  
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

**1. What is the medicine intended for?**

**Daivobet** ointment is used for the topical treatment of plaque psoriasis (psoriasis vulgaris).

**Therapeutic group:** other anti-psoriasis products for local treatment.

Psoriasis is caused by your skin cells being produced too quickly, which causes redness, scaling and thickening of the skin.  
**Daivobet** contains Calcipotriol and Betamethasone.  
Calcipotriol helps to control the rate of skin cell formation and Betamethasone reduces the inflammation.

**2. Before using the medicine**

**Do not use the medicine if:**

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| <ul style="list-style-type: none"><li>• You are hypersensitive (allergic) to the active ingredients (Calcipotriol, Betamethasone) or to any of the other ingredients this medicine contains (see section 6).</li><li>• You have problems with blood calcium levels (ask the doctor).</li><li>• You have certain types of psoriasis: erythrodermic, exfoliative or pustular, ask the doctor.</li><li>• As <b>Daivobet</b> contains a strong steroid, do not use it on areas of the skin affected by:<ul style="list-style-type: none"><li>◦ skin infections caused by viruses (e.g. cold sores or chicken pox)</li><li>◦ skin infections caused by a fungus (e.g. athlete's foot or ringworm)</li><li>◦ skin infections caused by bacteria</li><li>◦ skin infections caused by parasites (e.g. scabies)</li><li>◦ tuberculosis</li><li>◦ a red rash around the mouth (perioral dermatitis)</li><li>◦ thin skin, easily damaged veins, stretch marks</li><li>◦ ichthyosis (dry skin with fish-like scales)</li><li>◦ acne (pimples)</li><li>◦ severe flushing or redness of the facial skin (rosacea)</li><li>◦ ulcers or broken skin</li></ul></li></ul> |
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**Special warnings regarding the use of the medicine**

- **Before and during treatment with Daivobet, tell the doctor if:**
  - You are using other medicines that contain corticosteroids, as you may suffer from side effects.
  - You have used this medicine for a long time and plan to stop (there is a risk the psoriasis will get worse or "flare up" when steroids are stopped suddenly).
  - You suffer from diabetes (as the blood sugar/glucose level may be affected by the steroid).
  - Your skin becomes infected, as you may need to stop the treatment.
  - You suffer from a certain type of psoriasis called guttate psoriasis.
  - You experience blurred vision or other visual disturbances.
- Avoid use on more than 30% of the body or using more than 15 grams per day.
- Avoid use under bandages as it increases the absorption of the steroid.
- Avoid use on large areas of damaged skin, on mucus membranes or in skin folds (groin, armpit, under breasts) as it increases the absorption of the steroid.
- Avoid use on the face or on genitals as these areas are very sensitive to steroids.
- Avoid extended duration in the sun, extended use of solarium or any other forms of light treatment.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

**Children**

The medicine is not recommended for use in children under 18 years of age.

**Drug interactions**

**If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or planning to become pregnant, consult a doctor before using this medicine.  
If the doctor has allowed you to use **Daivobet** ointment while breastfeeding, take care and do not apply the ointment to the breast area.

**Driving and using machines**

This medicine should not have any effect on your ability to drive or use machines.

**Important information about some of the ingredients of this medicine**

**Daivobet** contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

**3. How to use this medicine**

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.  
The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is: apply once a day.  
Use in the evening may be more comfortable.  
**Do not exceed the recommended dose.** Do not swallow! For external use only.

**Instructions for use**

- Use only on areas affected by psoriasis and do not use on skin which is not affected by psoriasis.
- Remove the cap and check that the seal in the tube is whole before the first use of the ointment. Then pierce the seal in the tube with the piercer in the cap.
- Apply the ointment onto a clean finger.
- Gently rub on the skin to cover the area affected by psoriasis until most of the ointment has been absorbed into the skin.
- Do not bandage, tightly cover or wrap the treated area.
- Wash your hands well after using **Daivobet** (unless you are using the ointment to treat your hands), to avoid accidentally spreading the ointment to other areas of the body (particularly the face, scalp, mouth and eyes).
- Do not worry if some ointment accidentally gets on normal skin near the psoriasis, but wipe off the ointment if it spreads beyond the treated area.
- In order to achieve optimal results, it is recommended not to take a shower immediately after using **Daivobet**.
- After application, avoid contact with textiles which are easily stained by grease (e.g. silk).

**Duration of treatment**

- The recommended treatment period is 4 weeks, but the doctor can decide on a different treatment period.
- The doctor may decide on repeated treatment.
- Do not use on more than 30% of the body surface or more than 15 grams of **Daivobet** per day.

If you use other calcipotriol containing medicines, do not use more than 15 grams per day for the total amount of calcipotriol containing medicines, and the treated area should not exceed 30% of the total body surface.

**What can be expected when using Daivobet?**

Most of the patients notice results two weeks after beginning treatment, even if the psoriasis has not completely cleared at that time.

**If you used more Daivobet than you should**

Contact the doctor if you have used more than 15 grams per day. Excessive use can cause problems with the blood calcium levels, which usually return to normal after discontinuing treatment.  
The doctor may need to carry out blood tests to check that using too much ointment has not caused a problem with blood calcium levels. Excessive prolonged use can also cause the adrenal glands to stop working properly (the adrenal glands are found near the kidneys and produce hormones).  
If a child accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

**If you forgot to use the medicine**

If you forgot to use the ointment at the designated time, do not use a double dose to make up for a forgotten dose.  
Continue with the treatment as recommended by the doctor.  
Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the doctor.

**If you stop using the medicine**

It may be necessary to stop the use gradually, especially if you have used the ointment for a long time.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**  
**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

**4. Side effects**

Like any medicine, the use of **Daivobet** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Serious side effects**

Refer to a doctor immediately or as soon as possible with the appearance of the following side effects. You may have to stop the treatment.  
The following serious side effects have been reported for **Daivobet**:  
**Uncommon side effects** (effects that appear in 1-10 out of 1,000 users):

- Worsening of the psoriasis. If the psoriasis gets worse, refer to the doctor as soon as possible.

**Rare side effects** (effects that appear in 1-10 out of 10,000 users):

- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, **stop using Daivobet and refer to the doctor as soon as possible**.

Some serious side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in **Daivobet**. Refer to a doctor as soon as possible with the appearance of one or more of the serious side effects. These side effects are more likely to happen after long-term use, use in skin folds (e.g. groin, armpits or under breasts), use in covered areas or use on large areas of skin.

The side effects include:

- The adrenal glands may stop working properly. The symptoms include tiredness, depression and anxiety.
- Cataract (manifested by cloudy vision, difficulty seeing at night and sensitivity to light) or an increase in pressure inside the eye (manifested by eye pain, redness in the eye, decreased vision or cloudy vision).
- Infections (because your immune system, which fights infections, may be suppressed or weakened).
- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop using **Daivobet** and refer to a doctor as soon as possible.
- Impact on the metabolic control of diabetes (if you suffer from diabetes you may experience fluctuations in the blood sugar levels).

Serious side effects caused by the active ingredient calcipotriol in the medicine:

- Allergic reactions with deep swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and trouble breathing may occur. If you have an allergic reaction, **stop using Daivobet and refer immediately to the doctor or to a hospital emergency room**.
- Treatment with this medicine may cause the level of calcium in your blood or urine to increase (usually when too much ointment has been used). Signs of an increased calcium level in the blood are: increased secretion of urine, constipation, muscle weakness, confusion and coma.  
**This side effect can be serious and you should refer to a doctor immediately.** However, when the treatment is stopped, the calcium levels return to normal.

**Less serious side effects**

The following less serious side effects have been reported for **Daivobet**:

**Common side effects** (effects that appear in 1-10 out of 100 users):

- itching
- skin exfoliation

**Uncommon side effects** (effects that appear in 1-10 out of 1,000 users):

- skin pain or irritation
- rash with inflammation of the skin (dermatitis)
- redness of the skin due to widening of small blood vessels (erythema)
- inflammation or swelling of hair root (folliculitis)
- changes in skin color in the area where the ointment is applied
- rash
- burning sensation in the skin
- infection of the skin
- thinning of the skin
- appearance of red or purple spots on the skin (purpura or ecchymosis)

**Rare side effects** (effects that appear in 1-10 out of 10,000 users):

- Bacterial or fungal infection of the hair follicle (furuncle)
- Allergic reactions
- A high blood calcium level (hypercalcaemia)
- stretch marks
- sensitivity of the skin to light that manifests in a rash
- acne (pimples)
- dry skin
- rebound effect: a worsening of symptoms/psoriasis after ending treatment

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

- blurred vision

Less serious side effects caused by the active ingredient betamethasone in the medicine, especially with prolonged use, include the following side effects. You should tell the doctor as soon as possible if you notice one or more of them:

- thinning of the skin
- appearance of surface blood vessels or stretch marks
- changes in hair growth
- red rash around the mouth (perioral dermatitis)
- skin rash accompanied by inflammation or swelling (allergic contact dermatitis)
- golden colored gel-filled bumps (colloid milia)
- lightening of skin color (depigmentation)
- inflammation or swelling of the hair root (folliculitis)

Less serious side effects caused by the active ingredient calcipotriol in the medicine include:

- dry skin
- sensitivity of the skin to light manifested by a rash
- eczema
- itching
- skin irritation
- burning and stinging sensation in the skin
- redness of the skin due to widening of small blood vessels (erythema)
- rash
- rash with inflammation of the skin (dermatitis)
- worsening of psoriasis

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il>

**5. How to store the medicine**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store at a temperature above 25°C.  
The tubes may be used for up to 12 months from the day they are opened, with the exception of the 3 gram tube that may be used for 7 days from the day it is opened. It is recommended to write the date of opening on the package.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Additional information**

**In addition to the active ingredients, this medicine also contains:**

White soft paraffin, polyoxypropylene stearyl ether, liquid paraffin, all-rac- $\alpha$ -tocopherol, butylhydroxytoluene (E321).

**What the medicine looks like and what the package contains:**

a yellowish creme colored ointment.  
Approved package sizes: 3, 15, 30, 60, 100, 120 grams. Not all package sizes may be marketed.

**Manufacturer and address:** LEO Pharma A/S, Ballerup, Denmark  
Revised in July 2020.

**Drug registration number at the national drug registry of the Ministry of Health:**  
127-60-30600-00

Daivobet PIL PB0720-08

Registration holder: **Dexcel® Ltd.**  
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