

Package leaflet: Information for the patient

Calcipotriol Sandoz® 0,05 mg/ml, oplossing voor cutaan gebruik

calcipotriol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for
2. What you need to know before you use [Nationally completed name]
3. How to use [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Contents of the pack and other information

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] is used for local treatment of mild to moderate scalp psoriasis.

Psoriasis is when your skin cells are being produced too quickly. This causes scaling and redness. This solution helps bringing the rate at which your skin cells are produced back to normal.

2. What you need to know before you use [Nationally completed name]

Do not use [Nationally completed name]:

- if you are allergic to calcipotriol or to any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver or kidney impairment
- if you have a problem with your calcium metabolism or if the level of calcium in your body is too high. This solution can increase calcium levels in the blood.
- if you concomitantly use treatment with other medicinal product which increase your calcium level.

Warnings and precautions

Talk to your doctor or pharmacist before using **[Nationally completed name]**:

- the solution may cause irritation of the skin. If the scalp solution accidentally gets on your face. Wash it off immediately. If it gets in your eye, bathe the eye with water. Wash your hands after you have applied the solution.
- if you use more than 60 ml of **[Nationally completed name]** in a week, as you may develop high blood calcium levels. This may cause e.g. weakness, nausea, loss of appetite, and constipation (please see also section 3).
- if you are exposed to sunlight when using this solution. Any use of it with artificial UV light therapy (including sunbeds) should be discussed with your doctor first.
- if you know you have a type of psoriasis called generalised pustular psoriasis or erythrodermic exfoliative psoriasis. Ask your doctor if you are unsure.

Do not apply it on your face as it may cause skin irritation.

Do not cover the treated area with waterproof wrap.

You should avoid excessive exposure to sunlight when using this solution.

Use **[Nationally completed name]** with care in skin folds, as this may increase the risk of side effects.

[Nationally completed name] should not be used for guttate psoriasis, erythrodermic and pustular psoriasis because there is no experience.

Other medicines and **[Nationally completed name]**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you are using this cutaneous solution with other treatments for psoriasis, your doctor will tell you when to use it.

Concomitant use with systemic vitamin D products, calcium supplements, or other agents that can increase serum calcium concentrations such as thiazide diuretics, estrogens, anabolic steroids, and parathyroid hormone or parathyroid hormone analogs may increase the risk of clinically significant hypercalcemia.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

[Nationally completed name] should not be used during pregnancy unless clearly necessary.

Breast-feeding

It is not known if calcipotriol is excreted in breast milk. Your doctor will decide whether you can be given **[Nationally completed name]** during pregnancy and breast-feeding.

Fertility

There are no data on the effect of calcipotriol therapy on human fertility.

Driving and using machines:

No effect on the ability to drive and use machines is to be expected.

[Nationally completed name] contains 10 mg propylene glycol per ml of solution.
Propylene glycol may cause skin irritation.

3. How to use **[Nationally completed name]**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dose:

Adults

You should not apply more than 60 ml of this cutaneous solution in one week.
If you apply it together with cream or ointment containing calcipotriol, the total weekly amount of calcipotriol should not be more than 5 mg (for example 60 ml scalp solution plus 40 g of cream or ointment).

Method and route of administration:

[Nationally completed name] is intended for use on the skin (cutaneous use). It should be used on parts of scalp that are affected by psoriasis.

When you use the solution, tilt your head to make sure the solution does not run on to your face. It may help to part your hair before you use the solution. Remove the cap and place the nozzle through the hair on to an affected area of the scalp. Squeeze the bottle gently and apply a few drops. Rub in gently. One or two drops should cover an area about the size of a postage stamp. If you accidentally get the solution on your face, wash it off straight away. If you get the solution in your eyes rinse it out immediately with water. If you have any sterile saline, you could use it to bathe your eye afterwards. If your eye stays sore, you should see your doctor.

Wash your hands after you have applied this solution.

Frequency of administration

For the best results you should apply this solution twice a day, once in the morning and once in the evening.

Duration of treatment

Duration of treatment will be decided by your physician, but should not normally be longer than 22 weeks.

Use in children and adolescents (under 18 years)

[Nationally completed name] is not recommended for children and adolescents (under 18 years), because there is not enough experience with the use of this solution in these patients.

If you use more **[Nationally completed name] than you should**

If you have applied more solution than you should (more than 60 ml in a week), you should consult your doctor. Such usage may lead to high blood calcium levels, which may cause e.g. nausea, loss of appetite, constipation, vomiting, muscle weakness, lack of energy, tiredness and loss of consciousness.

If you forget to use [Nationally completed name]:

If you forget to use this solution at the right time, apply it as soon as you remember. Then go on as before. Do not apply more solution than usual to make up for a forgotten dose.

If you stop using [Nationally completed name]

Always consult your doctor if you are thinking about stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using this ointment and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms:

- Signs of allergy (uncommon side effect) such as hives, swelling of the face, eyelids, hands, feet or throat, difficulty breathing.

Very common (may affect more than 1 in 10 people):

- skin irritation

Common side effects (may affect up to 1 in 10 people):

- itching
- burning sensation
- contact dermatitis
- redness
- aggravated psoriasis
- skin inflammation
- skin peeling
- skin rash (incl. scaling, papules, pustules)
- pain in the area where the medicine is used

Uncommon side effects (may affect up to 1 in 100 people):

- dry skin
- hypersensitivity reactions
- eczema, rash
- changes in skin colour where the medicine is used
- infection in the hair follicle (folliculitis)
- hypercalciuria (too much calcium in the urine)
- seborrheic dermatitis (such as dandruff or cradle cap)
- temporary increased sensitivity to sunlight
- hypercalcaemia (too much calcium in the blood)

Rare side effects (may affect up to 1 in 1,000 people):

- You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion.
- itchy raised rash (hives)

If you accidentally get the cutaneous solution on your face, it can cause redness or irritation on your face or around your mouth.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [\[Nationally completed name\]](#)

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate or freeze.

Keep the bottle in the outer carton in order to protect from light.

Keep the cutaneous solution away from fire or flames (the alcohol base is inflammable).

Shelf life after first opening: 3 months.

Do not throw away any medicines via wastewater [or household waste](#). Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What [\[Nationally completed name\]](#) contains

The active substance is calcipotriol.

Each ml of cutaneous solution contains 0.05 mg (is equal to 50 micrograms) of calcipotriol.

The other ingredients are: sodium citrate, hypromellose, propylene glycol, isopropyl alcohol, levomenthol and water, purified.

What [\[Nationally completed name\]](#) looks like and contents of the pack

Clear, colourless solution with an odour of menthol.

The cutaneous solution comes in polyethylene bottles of 30 ml, 60 ml, [100 ml and 120 ml](#). The bottles are fitted with a polyethylene nozzle and closed with polypropylene screw caps.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikant

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:

Calcipotriol Sandoz 0,05 mg/ml is in het register ingeschreven onder RVG 101240.

Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

Duitsland: Calcipotriol HEXAL 0,05 mg/ml Lösung zur Anwendung auf der Haut
Nederland: Calcipotriol Sandoz 0,05 mg/ml, oplossing voor cutaan gebruik

Deze bijsluiter is voor het laatst goedgekeurd in september 2020.