PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Calcipotriol 50 micrograms/g ointment

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.

The name of your medicine is Calcipotriol 50 micrograms/g ointment but will be referred to as Calcipotriol throughout this leaflet.

What is in this leaflet

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

1. WHAT CALCIPOTRIOL IS AND WHAT IT IS USED FOR

Calcipotriol is used on the skin for local treatment of mild to moderately severe psoriasis (psoriasis vulgaris).

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CALCIPOTRIOL

Do not use Calcipotriol:
- 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 ointment can increase calcium levels in the blood.
- if you concomitantly use treatment with other medicinal products which increase your calcium level.

Warnings and precautions
Talk to your doctor or pharmacist before using Calcipotriol:
- if the patient is less than 18 years old, because there is not enough experience with the use of this ointment in children and adolescents.
- the ointment may cause irritation of the skin. Wash your hands after you have applied the ointment. Wash it off if it spreads too far on your normal skin.
- if you use more than 60ml of Calcipotriol 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 ointment. 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 ointment.
Use calcipotriol with care in skin folds, as this may increase the risk of side effects.

Calcipotriol should not be used for guttate psoriasis, erythrodermic and pustular psoriasis because there is no experience.

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

If you are using this ointment with other treatments for psoriasis (e.g. local corticosteroids), 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, oestrogens, 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
Calcipotriol 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 Calcipotriol during pregnancy and breastfeeding.

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

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

Calcipotriol contains propylene glycol
Propylene glycol may cause skin irritation.

3. HOW TO USE CALCIPOTRIOL

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

Dose:
For adults:
You should not apply more than 100 grams of this ointment in one week. If you apply it together with cream or solution containing Calcipotriol, the total weekly amount of Calcipotriol should not be more than 5mg (for example 40ml scalp solution plus 60g of cream or ointment).

Method and route of administration:
Calcipotriol is intended for use on the skin (cutaneous use).

Wash your hands before you apply this ointment. Remove the cap and check that the seal is not broken before you first use the ointment. If you have a 30 gram or 120 gram tube, you will need to break the seal by using the point in the back of the cap. Squeeze the ointment onto your finger or onto a patch of psoriasis. Apply ointment as a thin layer to the affected areas of your skin. Rub it in gently to cover the affected area. **Do not apply this ointment on your face** (please see also Section 4).

Wash your hands after you have applied this ointment, unless you are using the ointment to treat psoriasis on your hands. Try not to transfer the ointment from the areas you have treated to other areas of your body, especially your face.

If you are using a moisturiser, you should put it on first and wait for it to soak in before applying this ointment.

Frequency of administration
As monotherapy:
For the best results you should apply this ointment twice a day, once in the morning and once in the evening. Depending on the effect, your doctor may suggest you use the ointment once a day.

As combination therapy*:*
If you are using this ointment together with other treatments for psoriasis, your doctor will tell you how often and when to apply the ointment.

Duration of treatment:
You may notice an improvement after you have been using the ointment for about two weeks. The scaling or flaking usually goes away first. This will make your patches of psoriasis feel flatter. It will take longer for the redness of the skin to improve.
The maximum effect is usually achieved after 4-8 weeks.

Use in children and adolescents
Calcipotriol is not recommended for children and adolescents (under 18 years), because there is not enough experience with the use of this ointment in these patients.

If you use more Calcipotriol than you should
If you have applied more ointment than you should (more than 100 grams 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 Calcipotriol
If you forget to use this ointment at the right time, apply it as soon as you remember. Then go on as before. Do not apply more ointment than usual to make up for a forgotten dose.

If you stop using Calcipotriol
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.

Other possible side effects:
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 ointment 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CALCIPOTRIOL

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not refrigerate or freeze.
Store in the original package.
Discard 3 months after first opening.
Do not use this medicine after the expiry date, which is stated on the carton and tube label after 'Exp'. The expiry date refers to the last day of that month.

If the ointment becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Remember if your doctor tells you to stop using this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Calcipotriol contains
The active ingredient in Calcipotriol is calcipotriol.
Each gram of ointment contains 0.05mg calcipotriol (equivalent to 50 micrograms calcipotriol).
The other ingredients are macrogol stearyl ether, disodium edetate, sodium phosphate dibasic dihydrate, α-tocopheryl acetate, propylene glycol (E 490), light paraffin liquid, purified water and soft white paraffin.

What Calcipotriol looks like and contents of the pack
Calcipotriol is a white to off-white ointment. The ointment comes in an aluminium tube with polypropylene screw cap.

It is available in pack of 30g.

Manufactured by: Lek Pharmaceuticals d.d., Verovskova 57, 1526 Ljubljana, Slovenia. **Or**
Salutas Pharma GmbH, Lange Gohren 3, 39171 Osterweddingen, Germany.

Procured from within the EU and repackaged by the Product Licence holder: Smartway Pharmaceuticals Limited, 10 Lyon Road, London, SW19 2RL, UK.

Calcipotriol 50 micrograms/g ointment; PL 42332/0023

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Call **0208 545 7711** to obtain the leaflet in a format suitable for you.