Calcipotriol 50 micrograms/ml Scalp Solution
(calcipotriol)

Patient Information Leaflet
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 this leaflet?
1) What Calcipotriol 50 micrograms/ml Scalp Solution is and what it is used for
Calcipotriol 50 micrograms/ml Scalp Solution is used for the 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 bring the rate at which your skin cells are produced back to normal.

2) What you need to know before you use Calcipotriol 50 micrograms/ml Scalp Solution
Do not use Calcipotriol 50 micrograms/ml Scalp Solution:
• 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 comitantly use treatment with other medicinal products which increase your calcium level.

Warnings and precautions
Talk to your doctor or pharmacist before using Calcipotriol 50 micrograms/ml Scalp Solution:
• if the patient is less than 18 years old. There is no experience with the use of this solution in children and adolescents.
• 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 Calcipotriol Scalp Solution in a week, you may develop high blood calcium levels. This may cause e.g. weakness, nausea, loss of appetite, and constipation (please see also Section 4).
• 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.
• Do not cover the treated area with waterproof wrap.

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

Other medicines and Calcipotriol 50 micrograms/ml Scalp Solution
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.

Do not apply a cream or ointment containing salicylic acid to the skin where this cutaneous solution has to be applied, as it breaks down the active substance in this cutaneous solution.

Pregnancy and breast-feeding
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.

Calcipotriol 50 micrograms/ml Scalp Solution should not be used during pregnancy unless clearly necessary. It is not known if calcipotriol is excreted in breast-milk. Your doctor will decide whether you can be given Calcipotriol 50 micrograms/ml Scalp Solution during pregnancy and breast-feeding.

Short-term use on small surfaces is not expected to lead to effects on the breastfed child. In all other cases, breastfeeding is not recommended during treatment with calcipotriol.

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

Calcipotriol 50 micrograms/ml Scalp Solution contains propylene glycol, which may cause skin irritation.

3) How to use Calcipotriol 50 micrograms/ml Scalp Solution
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage:
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 40 ml scalp solution plus 60 g of cream or ointment).

Method and route of administration:
Calcipotriol 50 micrograms/ml Scalp Solution 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 onto your face. It may help to part your hair before you use the solution. Remove the cap and place the nozzle through the hair onto 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 your eye is sore, you should see your doctor.

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 solution, you could use it to bathe your eye afterwards. If your eye is sore, you should see your doctor.

Wash your hands after you have applied this solution.

Children and adolescents (under 18 years)
Calcipotriol 50 micrograms/ml Scalp Solution 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.

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.

**If you use more Calcipotriol 50 micrograms/ml Scalp Solution 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, depression, impaired thinking or memory, loss of consciousness, kidney dysfunction.

**If you forget to use Calcipotriol 50 micrograms/ml Scalp Solution**
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 Calcipotriol 50 micrograms/ml Scalp Solution**
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.

Like all medicines, this solution can cause allergic reaction in some patients (less than 1 in 10,000 people). Signs of allergy include hives, swelling of the face, eyelids, hands, feet or throat. If you get any of these symptoms after using this cutaneous solution, you should stop using the cutaneous solution and contact your doctor immediately.

Side effects could occur in approximately 25% of patients treated with Calcipotriol 50 micrograms/ml Scalp Solution. These reactions are usually mild. The most frequently reported are various transient skin reactions.

**Very common side effects** (may affect more than 1 in 10 people):
- skin irritation.

**Common side effects** (may affect up to 1 in 10 people):
- itching
- burning and stinging sensation
- dry skin
- redness
- rash.

**Uncommon side effects** (may affect up to 1 in 100 people):
- contact dermatitis
- eczema
- aggrivated psoriasis.

**Very rare side effects** (may affect up to 1 in 10,000 people):
- hypersensitivity reactions
- hypercalcaemia, hypercalciuria
- itchy raised rash (hives)
- temporary changes in your skin colour
- temporary increased sensitivity to sunlight
- facial and perioral dermatitis.

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, pharmacist or nurse. 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. By reporting side effects you can help provide more information on the safety of this medicine.

5) **How to store Calcipotriol 50 micrograms/ml Scalp Solution**
- Keep all medicines out of the sight and reach of children.
- Do not use Calcipotriol 50 micrograms/ml Scalp Solution 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. Keep the bottle in the outer carton. Protect from light. Do not refrigerate or freeze. Keep the cutaneous solution away from fire or flames (the alcohol base is inflammable).
- **Discard the opened bottle with any remaining solution after 3 months.**
- If the solution becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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 50 micrograms/ml Scalp Solution contains:**
The active substance is calcipotriol. Each ml of cutaneous solution contains 50 micrograms of calcipotriol.

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

**What Calcipotriol 50 micrograms/ml Scalp Solution looks like and contents of the pack**
The cutaneous solution is a clear, colourless solution with an odour of menthol. The cutaneous solution comes in a white polyethylene bottle fitted with a white polyethylene nozzle and closed with a white polypropylene screw cap. Each bottle contains 30ml of cutaneous solution.

Calcipotriol 50 micrograms/ml Scalp Solution is available in packs containing 1, 2, and 4 bottles.

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**Who makes and repackages your medicine**
Your medicine is manufactured by Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia or Salutas Pharma GmbH, Otto-von-Guericke, Allee 1, 39179 Barleben, Germany. Procured from within the EU and repackaged by Product Licence Holder: Primecrown Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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**Blind or partially sighted?**
**Is this leaflet hard to see or read?**
Call 020 8839 3000 to obtain the leaflet in a format suitable for you.