Package leaflet: Information for the user

Calcipotriol/Betamethasone 50 micrograms/g + 0.5 mg/g gel
calcipotriol/betamethasone

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Calcipotriol/Betamethasone gel is and what it is used for

Calcipotriol/Betamethasone gel contains the active substances calcipotriol and betamethasone. Calcipotriol helps to bring the rate of skin cell growth back to normal and betamethasone acts to reduce inflammation.

Calcipotriol/Betamethasone gel is used as a topical treatment of scalp psoriasis in adults and on the skin of other body areas to treat mild to moderate plaque psoriasis (psoriasis vulgaris) in adults.

Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling and thickness of your skin.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Calcipotriol/Betamethasone gel is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. What you need to know before you use Calcipotriol/Betamethasone gel

Do not use Calcipotriol/Betamethasone gel
- if you are allergic to calcipotriol, betamethasone or any of the other ingredients of this medicine (listed in section 6)
- if you have problems with calcium levels in your body (ask your doctor)
- if you have certain types of psoriasis: these are erythrodermic, exfoliative and pustular (ask your doctor).

As Calcipotriol/Betamethasone gel contains a strong steroid, do NOT use it on skin affected by:

- skin infections caused by viruses (e.g. cold sores or chicken pox)
- skin infections caused by a fungus (e.g. athlete's foot or ringworm)
- skin infections caused by bacteria
- skin infections caused by parasites (e.g. scabies)
- tuberculosis (TB)
- perioral dermatitis (red rash around the mouth)
- thin skin, easily damaged veins, stretch marks
- ichthyosis (dry skin with fish-like scales)
- acne (pimples)
- rosacea (severe flushing or redness of the skin on the face)
- ulcers or broken skin.

Warnings and precautions
Talk to your doctor or pharmacist before and during use of Calcipotriol/Betamethasone gel if:
- you are using other medicines that contain corticosteroids as you may get side effects
- you have used this medicine for a long time and plan to stop (as there is a risk your psoriasis will get worse or 'flare up' when steroids are stopped suddenly)
- you have diabetes mellitus (diabetes) as your blood sugar/glucose level may be affected by the steroid
- your skin becomes infected as you may need to stop your treatment
- you have a certain type of psoriasis called guttate psoriasis
- you experience blurred vision or other visual disturbances

Special precautions
- Avoid use on more than 30% of your body or using more than 15 grams per day
- Avoid using under a bathing cap, bandages or dressings as it increases the absorption of the steroid
- Avoid use on large areas of damaged skin, on mucous membranes, or in skin folds (groin, armpits, under breasts) as it increases the absorption of the steroid
- Avoid use on your face or genitals (sex organs) as they are very sensitive to steroids
- Avoid excessive sunbathing, excessive use of solarium and 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 and adolescents
Calcipotriol/Betamethasone gel is not recommended for the use in children and adolescents below the age of 18 years.

Other medicines and Calcipotriol/Betamethasone gel
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 for advice before using this medicine.

If your doctor has agreed that you can breast-feed, take care and do not apply Calcipotriol/Betamethasone gel to the breast area.

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

Calcipotriol/Betamethasone Gel contains butylated hydroxytoluene (E321)
Calcipotriol/Betamethasone gel contains butylated hydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Calcipotriol/Betamethasone contains hydrogenated castor oil
Calcipotriol/Betamethasone gel contains hydrogenated castor oil, which may cause skin reactions.

3. How to use Calcipotriol/Betamethasone gel

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

How to apply Calcipotriol/Betamethasone gel
Cutaneous use.

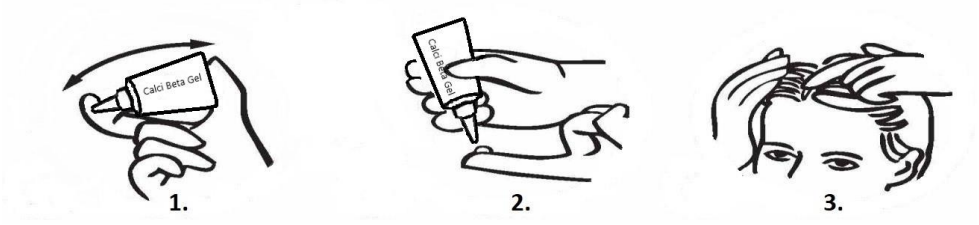
Instructions for proper use

- Use only on your psoriasis and do not use on skin which does not have psoriasis
- Shake the tube before use and remove the cap
- Squeeze the gel onto a clean finger or directly onto the area affected by psoriasis
- Apply Calcipotriol/Betamethasone gel to the affected area with your fingertips, and rub it in gently until the area affected by psoriasis is covered by a thin layer of gel
- Do not bandage, tightly cover or wrap the treated skin area
- Wash your hands well after using Calcipotriol/Betamethasone gel. This will avoid accidentally spreading the gel to other parts of your body (especially the face, mouth and eyes)
- Do not worry if some gel accidentally gets on normal skin near your psoriasis, but wipe it off if it spreads too far
- In order to achieve optimal effect, it is recommended not to take a shower or bath immediately after application of Calcipotriol/Betamethasone gel
- After applying the gel, avoid contact with textiles which are easily stained by grease (e.g. silk).

If you have scalp psoriasis

- Before applying Calcipotriol/Betamethasone gel to the scalp, comb the hair to remove any loose scales. Tilt your head to make sure the gel does not run onto your face. It may help to part your hair before you use the gel. Apply the gel to the affected area with your fingertips and rub it in gently.

Washing your hair before application of Calcipotriol/Betamethasone gel is not necessary.



Shake tube before use.	Apply a drop of the gel to fingertip.	Apply directly to scalp areas where you can feel the raised plaque and rub the gel on to the skin.

Depending on the affected area, 1-4 g (up to 1 teaspoon) is normally enough.

In order to achieve optimal effect, it is recommended that the hair is not washed immediately after application of Calcipotriol/Betamethasone gel. Let the gel remain on the scalp during the night or during the day. When washing hair after application the following instructions might be useful:

4.

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Apply a mild shampoo to the **dry hair**, especially to those areas where the gel was applied.	Leave the shampoo on the scalp for a couple of minutes before washing.	Wash your hair as usual.

If necessary, repeat steps 4-6 once or twice.

Duration of treatment

- Use the gel once a day. It may be more convenient to use the gel in the evening
- The normal initial treatment period is 4 weeks for scalp areas and 8 weeks for non-scalp areas
- Your doctor may decide on a different treatment period
- Your doctor may decide on repeated treatment
- Do not use more than 15 grams in one day.

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

What should I expect when I use Calcipotriol/Betamethasone gel?
Most patients see obvious results after 2 weeks, even if the psoriasis is not yet cleared at that point.

If you use more Calcipotriol/Betamethasone gel than you should
Contact your doctor if you have used more than 15 grams in one day.
Excessive use of Calcipotriol/Betamethasone gel may also cause a problem with calcium in your blood, which usually normalises when discontinuing treatment.
Your doctor may need to carry out blood tests to check that using too much gel has not caused a problem with calcium in your blood.
Excessive prolonged use can also cause your adrenal glands to stop working properly (the adrenal glands are found near the kidneys and produce hormones).

If you forget to use Calcipotriol/Betamethasone gel

Do not take a double dose to make up for a forgotten dose.

If you stop using Calcipotriol/Betamethasone gel
The use of Calcipotriol/Betamethasone gel should be stopped as indicated by your doctor. It may be necessary for you to stop this medicine gradually, especially if you have used it for a long time.

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.

Serious side effects
Tell your doctor/nurse immediately or as soon as possible if any of the following happen. You may have to stop your treatment.

The following serious side effects have been reported as uncommon (may affect up to 1 in 100 people):
- Worsening of your psoriasis. If your psoriasis gets worse, tell your doctor as soon as possible.

Some serious side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in Calcipotriol/Betamethasone gel. You should tell your doctor as soon as possible if any of the serious side effects occur. These side effects are more likely to happen after long-term use, use in skin folds (e.g. groin, armpits or under breasts), use under occlusion or use on large areas of skin.

The side effects include the following:
- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety
- Cataracts (signs are cloudy and foggy vision, difficulty seeing at night and sensitivity to light) or an increase in pressure inside the eye (signs are eye pain, red eye, decreased 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 Calcipotriol/Betamethasone gel and tell your doctor as soon as possible
- Impact on the metabolic control of diabetes mellitus (if you have diabetes you may experience fluctuations in the blood glucose levels).

Serious side effects known to be caused by calcipotriol
- 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 Calcipotriol/Betamethasone, **tell your doctor immediately or go to the casualty department at your nearest hospital**
- Treatment with this gel may cause the level of calcium in your blood or urine to increase (usually when too much gel has been used). Signs of increased calcium in the blood are excessive secretion of urine, constipation, muscle weakness, confusion and coma. **This can be serious, and you should contact your doctor immediately.** However, when the treatment is stopped, the levels return to normal.

Less serious side effects
The following less serious side effects have been reported for Calcipotriol/Betamethasone gel.

Common (may affect up to 1 in 10 people)
- Itching.

Uncommon (may affect up to 1 in 100 people)
- Eye irritation
- Burning sensation of the skin
- Skin pain or irritation
- Inflammation or swelling of the hair root (folliculitis)
- Rash with inflammation of the skin (dermatitis)
- Redness of the skin due to widening of the small blood vessels (erythema)
- Acne (pimples)
- Dry skin
- Rash
- Pustular rash
- Infection of the skin.

Rare (may affect up to 1 in 1,000 people)
- Allergic reactions
- Stretch marks
- Skin exfoliation
- Rebound effect: A worsening of symptoms/psoriasis after ending treatment.

Frequency not known (frequency cannot be estimated from the available data)
- White or grey hair can transiently change to a yellowish colour at the application site when used on the scalp
- Blurred vision

Less serious side effects caused by using betamethasone, especially for a long time, include the following. You should tell your doctor or nurse as soon as possible if you notice any of them
- Thinning of the skin
- Appearance of surface veins or stretch marks
- Changes in hair growth
- Red rash around the mouth (perioral dermatitis)
- Skin rash with inflammation or swelling (allergic contact dermatitis)
- Golden coloured gel-filled bumps (colloid milia)
- Lightening of skin colour (depigmentation)
- Inflammation or swelling of the hair root (folliculitis).

Less serious side effects known to be caused by calcipotriol include the following
- Dry skin
- Sensitivity of the skin to light resulting in a rash
- Eczema
- Itching
- Skin irritation
- Burning and stinging sensation
- Redness of the skin due to widening of the small blood vessels (erythema)
- Rash
- Rash with inflammation of the skin (dermatitis)
- Worsening of psoriasis.

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 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/Betamethasone gel

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 tube and carton after EXP. The expiry date refers to the last day of that month
Do not refrigerate.
Discard the tube with any remaining gel 6 months after first opening.

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 protect the environment.

6. Contents of the pack and other information

What Calcipotriol/Betamethasone gel contains
The active substances are calcipotriol and betamethasone.
One gram of gel contains 50 micrograms calcipotriol (as monohydrate) and 0.5 mg betamethasone (as dipropionate).

The other ingredients are liquid paraffin, polyoxypropylene stearyl ether, hydrogenated castor oil, butylhydroxytoluene (E321).

What Calcipotriol/Betamethasone gel looks like and contents of the pack
Calcipotriol/Betamethasone gel is an almost clear, colourless to slightly off-white gel filled in a white cylindrical HDPE tube with a white PP screw cap.
The tube is placed in a carton.

Pack sizes:
1 tube of 30 g.
1 tube of 60g.
Multipacks containing 60 g (2 tubes of 30 g) and 120 g (2 tubes of 60 g)
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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Manufacturer
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