Package leaflet: Information for the user

Calcipotriol/Betamethasone Rowex 50 microgram/g + 0.5 mg/g Ointment

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

Calcipotriol/Betamethasone Rowex ointment is used on the skin to treat 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.
Calcipotriol/Betamethasone Rowex ointment contains calcipotriol and betamethasone. Calcipotriol helps to bring the rate of skin cell growth back to normal and betamethasone acts to reduce inflammation.

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

Do not use Calcipotriol/Betamethasone Rowex
• 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 the body (ask your doctor)
• If you have certain types of psoriasis: these are erythrodermic, exfoliative and pustular (ask your doctor).
As Calcipotriol/Betamethasone Rowex contains a strong steroid do NOT use 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 using Calcipotriol/Betamethasone Rowex 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.

<u>Special precautions</u>
• Avoid use on more than 30% of your body or using more than 15 grams per day
• Avoid using under 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 the 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.

Contact your doctor if you experience blurred vision or other visual disturbances.

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
Calcipotriol/Betamethasone Rowex is not recommended for the use in children below the age of 18 years.

Other medicines and Calcipotriol/Betamethasone Rowex
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility
Do not use Calcipotriol/Betamethasone Rowex if you are pregnant (or might be pregnant) or if you are breast-feeding, unless you have agreed it with your doctor first. If your doctor has

agreed that you can breast-feed, take care and do not apply Calcipotriol/Betamethasone Rowex to the breast area.
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 taking any medicine.

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

3. How to use Calcipotriol/Betamethasone Rowex

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

How to put on Calcipotriol/Betamethasone Rowex: Cutaneous use.

Instruction for proper use
- Use only on your psoriasis and do not use on skin which does not have psoriasis
- Remove the cap and check that the seal in the tube is not broken before you first use the ointment
- To break the seal, use the point in the back of the cap
- Squeeze the ointment onto a clean finger
- Rub gently into your skin to cover the affected area of psoriasis until most of the ointment has disappeared into the skin
- Do not bandage, tightly cover or wrap the treated skin area
- Wash your hands well after using Calcipotriol/Betamethasone Rowex (unless you are using the ointment to treat your hands). This will avoid accidentally spreading the ointment to other parts of your body (especially the face, scalp, mouth and eyes)
- Do not worry if some ointment 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 Rowex ointment
- After applying the ointment avoid contact with textiles which are easily stained by grease (e.g. silk).

Duration of treatment
- Use the ointment once a day. It may be more convenient to use the ointment in the evening.
- The normal initial treatment period is 4 weeks but 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 Rowex?
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 Rowex than you should
Contact your doctor if you have used more than 15 grams in one day.
Excessive use of Calcipotriol/Betamethasone Rowex may 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 ointment has not caused a problem with calcium in your blood.
Excessive prolonged use can also cause your adrenal glands to stop working properly (these are found near the kidneys and produce hormones).

If you forget to use Calcipotriol/Betamethasone Rowex
Do not take a double dose to make up for a forgotten dose.

If you stop using Calcipotriol/Betamethasone Rowex
The use of Calcipotriol/Betamethasone Rowex 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 happens. You may have to stop your treatment.

The following serious side effects have been reported for Calcipotriol/Betamethasone Rowex:

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.

Rare (may affect up to 1 in 1,000 people)
- Pustular psoriasis may occur (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop using Calcipotriol/Betamethasone Rowex and 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 Rowex. 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 Rowex 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 Rowex, **tell your doctor immediately or go to the casualty department at your nearest hospital.**
- Treatment with this ointment may cause the level of calcium in your blood or urine to increase (usually when too much ointment has been used). Signs of increased calcium in 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.

<u>Less serious side effects</u>
The following less serious side effects have been reported for Calcipotriol/Betamethasone Rowex:

Common side effects (may affect up to 1 in 10 people)
- Itching
- Skin exfoliation.

Uncommon (may affect up to 1 in 100 people)
- Skin pain or irritation
- Rash with inflammation of the skin (dermatitis)
- Redness of the skin due to widening of the small blood vessels (erythema)
- Inflammation or swelling of the hair root (folliculitis)
- Changes in skin colour in the area you have used the ointment
- Rash
- Burning sensation
- Infection of the skin
- Thinning of the skin

• Appearance of red or purple discolouration on the skin (purpura or ecchymosis).

Rare (may affect up to 1 in 1,000 people)
• Bacterial or fungal infection of hair follicle (Furuncle)
• Allergic reactions
• Hypercalcaemia
• Stretch marks
• Sensitivity of the skin to light resulting in a rash
• Acne (pimples)
• Dry skin
• Rebound effect: A worsening of symptoms/psoriasis after ended treatment.

Not known (frequency cannot be estimated from the available data)
• 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 blood vessels 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 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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Calcipotriol/Betamethasone Rowex

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 carton and tube after EXP. The expiry date refers to the last day of that month.

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

The tube should be discarded 1 year after first opening. Write the date you first opened the tube in the space provided on the carton.

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 Rowex contains

- The active substances are: Calcipotriol and betamethasone.

One gram of ointment contains 50 micrograms of calcipotriol (as monohydrate) and 0.5 mg of betamethasone (as dipropionate).

- The other ingredients are: All rac-α-tocopherol (E307), Oleyl alcohol, Paraffin light liquid, Paraffin white soft.

What Calcipotriol/Betamethasone Rowex looks like and the contents of the pack
Calcipotriol/Betamethasone Rowex is an off white ointment. The ointment is filled in the container with aluminium/epoxyphenol tubes with polyethylene or polypropylene screw caps.

Pack sizes: Tubes containing 15g, 30g, 60g and 120g of ointment.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co, Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Salutas Pharma GmbH, Betriebsstaette, Osterweddingen, Lange Goehren 3, D-39171, Suelzetal, Germany.
Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
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This medicinal product is authorised in the Member States of the EEA under the following names:

BE	Crysalis 50 microgram/ 0.5 mg/g zalf
DE	Calcipotriol comp HEXAL
DK	Calcipotriol/Betamethasone Sandoz
EE	Cabemet
ES	Prenamid 50 microgramos/g + 0,5mg/g pomada
FI	Calcipotriol/Betamethasone Sandoz 50/500 mikrog/g voide
FR	CALCIPOTRIOL/BETAMETHASONE SANDOZ 50 microgrammes/0,5 mg/g, pommade
IE	Calcipotriol/Betamethasone Rowex 50 microgram/g + 0.5 mg/g Ointment
IT	Zoripot
LT	Cabemet 50 mikrogramų/0,5 mg/g tepalas
LV	Cabemet 50 mikrogrami/0,5 mg/g ziede
MT	Calcipotriol/Betamethasone Sandoz Ointment 50mcg per g/500mcg per g
NL	Calcipotriol/Betamethason Sandoz 50 microgram/g + 0,5 mg/g, zalf
NO	Calcipotriol/Betamethasone Sandoz 50 mikrogram/g + 0,5 mg/g salve
PT	Dilabion
SE	Calcipotriol/Betamethasone Sandoz 50 mikrogram/g + 0,5 mg/g salva
SI	SOREL COMBO 50 mikrogramov/500 mikrogramov v 1 g mazilo
UK (Northern Ireland)	Calcipotriol/Betamethasone Sandoz 50 micrograms per g / 500 micrograms per g ointment

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