

PATIENT INFORMATION LEAFLET

PSOCAL BETA 0.005% + 0.05% Ointment

For external use.

- **Active substance(s):** Each gram of ointment contains 0.0522 mg calcipotriol monohydrate equivalent to 0.05 mg calcipotriol and 0.643 mg betamethasone dipropionate equivalent to 0.5 mg betamethasone.
- **Excipient(s):** Liquid paraffin, polyoxypropylene-11-stearyl ether (contains butyl hydroxytoluene (E321)), vitamin E (α -tocopherol) and white soft paraffin.

Read this PATIENT INFORMATION 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this Leaflet:

- 1. What PSOCAL BETA is and what it is used for?**
- 2. Before you use PSOCAL BETA**
- 3. How to use PSOCAL BETA?**
- 4. Possible side effects**
- 5. How to store PSOCAL BETA?**

1. What PSOCAL BETA is and what it is used for?

- PSOCAL BETA contains calcipotriol (a substance similar to vitamin D) and betamethasone (a steroid) active substances. Calcipotriol allows the growth rate of skin cells to return to normal. Betamethasone, a corticosteroid, helps reduce inflammation (should not be confused with anabolic steroids used incorrectly by some bodybuilders and athletes).
- PSOCAL BETA is used for the treatment of psoriasis vulgaris. Psoriasis occurs when skin cells rapidly begin to proliferate. This causes redness, scaling and thickening of the skin.
- PSOCAL BETA treats symptoms of psoriasis and helps to normalize the rapidly proliferating cells in the skin.
- PSOCAL BETA is presented in 30 gram aluminum tubes in ointment form.

2. Before you use PSOCAL BETA

Do not apply PSOCAL BETA to the face. If accidentally smudged to face, wash your face.

DO NOT use PSOCAL BETA

If;

- you have allergic or hypersensitivity to calcipotriol, betamethasone, or any of the excipients of the ointment
- you have a known calcium metabolism disorder (consult your doctor)
- There are other types of psoriasis that are marked with redness, scaling, and blistering (consult your doctor)
- Infections caused by viruses (e.g. cold sores or chickenpox)
- Infections caused by bacteria
- Parasitic infections (e.g. scabies)
- Tuberculosis
- Fungal infections (e.g., fungal disease on foot or itchy fungal disease which is usually round or oval on the skin)
- Acne
- Redness of the skin on the face (rosacea)
- Red rash around the mouth
- Thinning of the skin, the appearance of surface veins or stretch marks
- Inherited skin disease that is marked with drying, hardening and scaling
- Injured or wounded skin

Use PSOCAL BETA with CAUTION

Consult your doctor or pharmacist before you start using this medicine in the following situations:

- If you are using other medicines that contain corticosteroids as you may get side effects
- If 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)
- If you have diabetes mellitus (diabetes) as your blood sugar/glucose level may be affected by the steroid.
- If your skin becomes infected as you may need to stop your treatment.
- If have a certain type of psoriasis called guttate psoriasis.

Special precautions:

- Wash your hands after using it to avoid contact with the face, mouth, eyes and other possible contact.
- Avoid use more than 100 g / week to prevent increase of your blood calcium level.
- Avoid use bandages or dressing because it will increase the absorption of steroids.
- Avoid use on large areas of damaged skin or in skin folds (groin, armpits, under breasts) as it increases the absorption of steroids.
- 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.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using PSOCAL BETA with food and drink:

You can use PSOCAL BETA before or after food and drink. There is no problem as it is applied on the skin.

Pregnancy

Ask your doctor or pharmacist for advice before using the medicine.

Tell your doctor that you are pregnant or you may be pregnant because your doctor will want to take this into account before prescribing PSOCAL BETA.

If you are pregnant or think you may be pregnant, you should not use PSOCAL BETA unless it is required by your doctor.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before using the medicine.

The safety of the use of the ointment during breastfeeding has not been determined.

If your doctor has allowed you to use this product during breastfeeding, carefully apply it and do not apply PSOCAL BETA to your breast / nipple.

Driving and using machines

PSOCAL BETA has no known effect on the ability to drive and use machines, or it can have a minimal impact.

Important information about some excipients in PSOCAL BETA

PSOCAL BETA contains butyl hydroxytoluene (E321) as an excipient. Butyl hydroxytoluene can cause local skin reactions (e.g. contact dermatitis) or irritation in the eyes and mucous membranes.

Using with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use PSOCAL BETA?**• Instructions for appropriate method and dose/frequency of administration:**

You should always use PSOCAL BETA as your doctor tells you. If you are not sure, consult your doctor or pharmacist again.

- Apply PSOCAL BETA once a day, preferably in the evenings.
- Normal initial treatment duration is 4 weeks; but your doctor can decide on a different treatment period.
- Your doctor will decide if the treatment is to be repeated.
- Do not use more than 15 g in one day.

If you are using other medications containing calcipotriol, the total amount of calcipotriol drugs should not exceed 15 grams in one day and 100 grams in a week.

• **Route and method of administration:**

- Use only on your psoriasis and do not use on skin which does not have psoriasis.
- Wash your hands before using PSOCAL BETA, squeeze the cream on the tip of your clean finger and apply it onto the area affected by psoriasis. Gently rub until a large amount of the applied PSOCAL BETA is absorbed by your skin.
- Do not bandage, tightly cover or wrap the treated skin area.
- Wash your hands after application (if you are not using it for the treatment of psoriasis in your hands) so that there are no undesirable transmission in the face and other body parts. This will avoid accidentally spreading the gel to other parts of your body (especially face, head, 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 PSOCAL BETA.
- As PSOCAL BETA is an oily product, do not wear it immediately after applying (e.g. silk).

• **Different age groups:**

Use in children:

PSOCAL BETA is not recommended for use in children and adolescents under 18 years of age. Its use is not recommended in the childhood age group unless it is mandatory.

• **Special conditions:**

Kidney/liver failure:

It should not be used in patients with severe kidney or liver disease.

If you have the impression that the effect of PSOCAL BETA is too strong or too weak, talk to your doctor or pharmacist.

If you used more PSOCAL BETA than you should:

If you may have taken more PSOCAL BETA than you should, talk to a doctor or pharmacist.

If you have used more than 15 g a day, contact your doctor.

Long-term, excessive use of PSOCAL BETA can often cause problems (increases) in blood calcium levels, which usually normalizes when discontinuing treatment. Your doctor may need to carry out blood tests to detect this condition.

Excessive prolonged use can also cause your adrenal glands to stop working properly.

If you forget to use PSOCAL BETA:

Do not take double dose to balance the missed doses.

If you forget to use PSOCAL BETA at the correct time, use soon as you remember and continue treatment as before.

If you stop using PSOCAL BETA:

The use of PSOCAL BETA should be discontinued as recommended by your physician. Especially after long use, treatment should be terminated by gradually reducing the dose.

If you have any additional questions regarding the use of PSOCAL BETA, consult your doctor or pharmacist.

4. Possible side effects?

Like all medicines, PSOCAL BETA can cause side effects in people sensitive to the ingredients in its contents.

Side effects are classified according to frequency of occurrence as follows:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but more than 1 or 1 in 100 patients

Uncommon: may be seen less than 1 in 100 patients but more than 1 or 1 in 1000 patients

Rare: may be seen less than 1 in 1000 patients but more than 1 or 1 in 10000 patients

Very rare: may be seen less than one in 10000 patients.

Unknown: It cannot be estimated from the available data.

If you notice any of the following side effects, tell your doctor immediately. You may need to stop your treatment:

- 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 experience an allergic reaction stop using PSOCAL BETA **and inform your doctor immediately or contact your nearest hospital emergency room.**
- During your PSOCAL BETA treatment, you may have elevated levels of calcium in your blood or your urine (usually when too much ointment is applied). The increase in blood calcium levels is manifested by the symptoms of bone pain, constipation, decreased appetite, vomiting and nausea. **Take these seriously and contact your doctor immediately.** However, when treatment is terminated, the levels return to normal.
- If your psoriasis worsens, contact your doctor immediately.
- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet) may occur. If you notice this, discontinue use of PSOCAL BETA and inform your doctor immediately.

These very serious side effects are all rare.

Other side effects of PSOCAL BETA are:

Common

- Exfoliating of the skin
- Itching

Uncommon

- Skin infection
- Folliculitis
- Thinning of the skin
- Exacerbation of psoriasis
- Rash with swelling, pain and redness on the skin (dermatitis)
- Redness of the skin due to widening of the small blood vessels
- Rash
- Redness or bruising of the skin
- Burning sensation on the skin
- Skin irritation
- Discoloration and pain at the application site

Rare

- Furuncle
- Hypersensitivity of the skin
- Increase in blood calcium levels
- Cracks
- Light sensitivity
- Acne (acne)
- Skin dryness
- Rebound effect

Side effects known to be caused by calcipotriol are:

- Skin dryness
- Sensitivity of the skin to light resulting in a rash
- Skin disease (eczema) with symptoms such as redness, swelling, vesicles (water blister), itching,
- Itching
- Skin irritation
- Burning and stinging sensation on the skin
- Redness of the skin due to widening of the small blood vessels (erythema)
- Rash
- Rash with swelling, pain and redness on the skin (dermatitis)
- Worsening of psoriasis

Side effects known to be caused by Betamethasone are:

- The function of your adrenal glands may completely stop. The symptoms are fatigue, 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 (as a result of weakened or suppressed immune systems).

- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, discontinue use of PSOCAL BETA and inform your doctor immediately.
- If you have diabetes, your blood sugar levels may fluctuate.

These side effects are more commonly seen after prolonged use, at skin folds (eg inguinal, armpit or under breast), with closed dressing technique, or application on large skin surfaces.

Other side effects known to be caused by betamethasone are:

- Thinning of the skin
- Appearance of surface veins or cracks
- Changes in hair growth
- Red rash around the mouth (perioral dermatitis)
- Skin rashes (allergic contact dermatitis) seen as inflammation or swelling
- Bright brown gel-looking nodules (colloid milia)
- Lightening of skin color
- Swelling or inflammation of hair follicles (folliculitis)

If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.

5. How to store PSOCAL BETA

Keep PSOCAL BETA in the original package and out of the reach and sight of children.

Store at room temperature below 25°C, and away from direct light and humidity.

Use in accordance with the expiry date.

Do not use PSOCAL BETA after the expiry date which is stated on the package.

The tube can be used up to 12 months after it is opened, provided it does not exceed the expiration date. Therefore, note the date on which the tube was opened.

Marketing authorization holder:

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