

This medicine can be sold with a physician's prescription only

## XAMIOL® GEL - For use on the skin and scalp

### Active ingredients:

Calcipotriol 50 mcg/g (as hydrate)  
Betamethasone 0.5 mg/g (as dipropionate)

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

**Read this entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

### 1. What is the medicine intended for?

**Xamiol gel** is used for topical treatment of psoriasis of the scalp and for the treatment of mild to moderate psoriasis vulgaris of other body areas in adults 18 years of age and older.

### Therapeutic group:

Calcipotriol - a synthetic vitamin D derivative used for external treatment of psoriasis.  
Betamethasone - a synthetic corticosteroid.

Psoriasis is caused by the skin cells being produced too quickly, which causes redness, formation of scales and thickening of the skin. Calcipotriol helps control the rate of skin cell formation and Betamethasone reduces inflammation.

### 2. Before using the medicine

#### Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients (Calcipotriol, Betamethasone) or to any of the other ingredients this medicine contains (see section 6).
- You have problems with calcium levels in the blood (ask the doctor).
- You have certain types of psoriasis: erythrodermic, exfoliative or pustular psoriasis, ask the doctor.
- As **Xamiol** 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
  - red rash around the mouth (perioral dermatitis)
  - thin skin, easily damaged veins, stretch marks
  - ichthyosis (dry skin with fish-like scales)
  - acne (pimples)
  - severe flushing or redness of the skin on the face (rosacea)
  - ulcers or broken skin

#### Special warnings regarding the use of the medicine

- **Before and during the treatment with Xamiol, tell the doctor 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 suffer from 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.
- Avoid use on more than 30% of your body or using more than 15 grams per day.
- Avoid use under a bathing cap or bandages 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 these areas are very sensitive to steroids.
- Avoid extended duration in the sun, extended use of solarium (tanning bed for example) or any 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 completely remove it.

### Children

This medicine is not intended for the use in children below 18 years of age.

### Drug interactions

**If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

**Pregnancy, breastfeeding and fertility**  
If you are pregnant or breastfeeding, think you may be pregnant or planning to become pregnant, consult a doctor before using this medicine. If the doctor has agreed that you can use **Xamiol** while breastfeeding, take care and do not apply the gel to the breast area.

### Driving and using machines

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

### Important information about some of the ingredients of this medicine

Xamiol contains butylhydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

### 3. How to use this medicine

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The medicine is intended to use on skin (cutaneous use).

#### Instructions for use

- Use the gel only on areas affected by psoriasis and do not use on skin which is not affected by psoriasis.
- Shake the bottle before use and remove the cap.
- Apply the gel on a clean finger or directly to the area affected by psoriasis.
- Apply the gel to the affected area with your fingertips, and rub it in gently until the affected area by psoriasis is covered by a thin layer of the gel.
- Do not bandage, tightly cover or wrap the treated area.
- Wash your hands well after using **Xamiol**, in order to 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 the psoriasis, but wipe it off if it spreads beyond the treated area.
- In order to achieve optimal results, it is recommended not to take a shower immediately after application of **Xamiol**.
- After application, avoid contact with textiles which are easily stained by grease (e.g. silk).

#### If you have scalp psoriasis:

Before applying the gel to the scalp, comb the hair to remove any loose scales. Tilt your head to avoid the gel running onto your face. Parting your hair before using **Xamiol** may help. Apply the gel to the affected area with your fingertips, and rub it in gently.

**Washing your hair before application of Xamiol is not necessary.**



Shake the bottle before use.



Apply a drop of **Xamiol** to fingertip.



Apply directly to the affected scalp area and rub the gel on to the skin. Depending on the affected area, 1- 4 gram (up to 1 teaspoon) is sufficient enough for treatment of the scalp.

**In order to achieve optimal results, it is recommended that the hair is not washed immediately after application of Xamiol. Let Xamiol remain on the scalp during the night or day.**

**When washing hair after application, the following instructions might be useful:**



Apply a mild shampoo to **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

- The dosage and administration will be determined by the doctor only. The recommended dosage is usually: apply once a day.
  - **Do not exceed the recommended dose.** Do not swallow! For external use only.
  - It may be more convenient to use the gel in the evening.
  - The normal initial treatment period is 4 weeks for scalp area and 8 weeks for other body areas. The doctor can decide on a different treatment period. The doctor may also decide on repeated treatment.
  - Do not use on more than 30% of the body surface or more than 15 gram of **Xamiol** per day.
- If you use other Calcipotriol containing medicines, do not use more than 15 gram per day for the total amount of Calcipotriol containing medicines, and the treated area should not exceed 30% of the total body surface.

#### What should I expect when I use Xamiol?

Most patients observe results after 2 weeks from the beginning of treatment even if the psoriasis has not completely cleared by this time.

#### If you used more Xamiol than you should

Contact your doctor if you have used more than 15 grams in one day. Excessive use can cause problems with the blood calcium levels, which usually return to normal after cessation of the treatment. The doctor may need to carry out blood tests to check that using too much gel has not caused a problem with calcium levels in the blood. Excessive prolonged use can also cause the adrenal glands to stop working properly (the adrenal glands are found near the kidneys and produce hormones).

If a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

#### If you forgot to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose to make up for a forgotten dose. Continue with the treatment as recommended by the doctor.

#### If you stop taking the medicine

Even if there is an improvement in your health, do not stop the treatment with the gel without consulting the doctor. It may be necessary for you to stop this medicine gradually, especially if you have used it for a long time.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

### 4. Side effects

Like any medicine, the use of **Xamiol** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

#### Serious side effects

**Refer to a doctor immediately or as soon as possible with the appearance of the following.** You may have to stop your treatment.

The following serious side effects have been reported for **Xamiol**.

**Uncommon side effects** (effects that appear in 1-10 out of 1,000 users):

- Worsening of psoriasis. If your psoriasis gets worse, tell the doctor as soon as possible.

Some serious side effects are known to be caused by Betamethasone (a strong steroid), one of the ingredients in **Xamiol**. You should tell the 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:

- The adrenal glands may stop working properly.
- Signs are tiredness, depression and anxiety.
- Cataract (signs are cloudy vision, difficulty seeing at night and sensitivity to light) or an

increase in pressure inside the eye (signs are eye pain, redness of the eye, decreased vision 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 Xamiol and refer to a doctor as soon as possible.**
- Impact on the metabolic control of diabetes (if you have diabetes you may experience fluctuations in the blood glucose levels).

Serious side effects known to be caused by the active ingredient Calcipotriol in the medicine:

- 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 Xamiol and refer immediately to a doctor or to a hospital emergency room.**
- Treatment with this medicine 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 levels in the blood are: excessive secretion of urine, constipation, muscle weakness, confusion and coma. **This side effect can be serious and you should refer to a doctor immediately.** However, when the treatment is stopped, the levels of calcium return to normal.

#### Less serious side effects

The following less serious side effects have been reported for **Xamiol**.

**Common side effects** (effects that appear in 1-10 out of 100 users):

- itching

**Uncommon side effects** (effects that appear in 1-10 out of 1,000 users):

- 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 side effects** (effects that appear in 1-10 out of 10,000 users):

- allergic reactions
- stretch marks
- skin exfoliation
- rebound effect: a worsening of symptoms/psoriasis after ended treatment

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

- white or grey hair can transiently change to a yellowish color at the application site when used on the scalp
- blurred vision

Less serious side effects caused by the active ingredient Betamethasone in the medicine, especially after prolonged use, include the following. You should tell the doctor 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 colored gel-filled bumps (colloid milia)
- lightening of skin color (depigmentation)
- inflammation or swelling of the hair root (folliculitis)

Less serious side effects known to be caused by the active ingredient Calcipotriol in the medicine 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

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il>

### 5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (EXP.) stated on the package. The expiry date refers to the last day of that month.

**Storage conditions:** Keep the bottle in the outer carton in order to protect from light. Do not refrigerate. Store at a temperature below 25°C. Can be used up to 6 months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Additional information

**In addition to the active ingredients, this medicine also contains:**

Liquid paraffin, polyoxypropylene stearyl ether, hydrogenated castor oil, butylhydroxytoluene (E321), all-rac- $\alpha$ -tocopherol.

**What the medicine looks like and what the package contains:**

A bottle containing almost clear, colorless gel. Approved package sizes: 15, 30, 60 gram in package. Not all the package sizes may be marketed.

**Manufacturer and address:** LEO Pharma A/S, Ballerup, Denmark

Revised in October 2020.

**Drug registration number at the national drug registry of the Ministry of Health:** 144-25-32996-01

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