XAMIOL® GEL

Calcipotriol monohydrate / Betamethasone dipropionate (50 mcg/g / 0.5mg/g)

What is in this leaflet

1. What *Xamiol® Gel* is used for
2. How *Xamiol® Gel* works
3. Before you use *Xamiol® Gel*
4. How to use *Xamiol® Gel*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Xamiol® Gel*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Xamiol® Gel* is used for

Xamiol® Gel is used as a topical treatment of scalp and non-scalp plaque psoriasis vulgaris in adults. Psoriasis is the condition where your skin develops red patches and silver coloured scaly patches. The scaly patches are dead cells that would normally fall off your skin without you noticing. Psoriasis causes the cells in your skin grow too quickly.

How *Xamiol® Gel* works

Xamiol® Gel contains calcipotriol and betamethasone. Calcipotriol helps to reduce the skin cell growth and bring the rate of skin cell growth back to normal and betamethasone acts to reduce inflammation.

Before you use *Xamiol® Gel*

- *When you must not use it*

Do not use *Xamiol® Gel*

- If you are allergic (hypersensitive) to calcipotriol, betamethasone or any of the other ingredients of *Xamiol® Gel.*
- If you have problems with calcium levels in your body (ask your doctor).
- If you have certain types of psoriasis: these are guttate, erythrodermic, exfoliative and pustular (ask your doctor).
- If you have serious liver or kidney disease.

As *Xamiol® Gel* contains a strong steroid do NOT use on skin affected by

- infections caused by viruses (e.g. cold sores or chicken pox)
- infections caused by a fungus (e.g. athlete's foot and ringworm)
- infections caused by bacteria
- infections caused by parasites (e.g. scabies)
- tuberculosis (an infectious bacterial disease that mainly affects the lungs) or syphilis (a bacterial infection usually spread by sexual contact)
- 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
- itching of the anus (back passage) or genitals (sex organs).

Pregnancy and lactation

Do not use *Xamiol® Gel* if you are pregnant (or might be pregnant) or 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 *Xamiol® gel* to the breast area.

Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

Take special care with *Xamiol® Gel*

Before using this medicine, tell your doctor/nurse/pharmacist if:

- you are using other medicines that contain steroids, 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.

Use in children

Xamiol® Gel is not recommended for use in children below the age of 18 years.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

How to use *Xamiol® Gel*

- How to put on *Xamiol® Gel*: Cutaneous use

Instruction for proper use

- Use only on your psoriasis and do not use on skin which do not have psoriasis
- Shake the bottle before use and remove the cap
- Wash your hands well after using *Xamiol® 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 *Xamiol® Gel*

If you have scalp psoriasis

- For treatment of the scalp usually an amount between 1g and 4g per day is sufficient (4g corresponds to one teaspoon)
- In order to achieve optimal effect, it is recommended that the hair is not washed immediately after application of *Xamiol® Gel*. Let *Xamiol® Gel* remain on scalp during the night or during the day.

- *How much to use*

Always use *Xamiol® Gel* exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

DK/H/279/001/IA/032/G - 18 Mar 2011

- *When to use it*

Use the gel once a day.

If you use other calcipotriol containing medicines, the total amount of calcipotriol medicines must not exceed 15g per day (4g corresponds to 1 teaspoon) and the area treated should not exceed 30% of the total body surface.

- *How long to use it*

- 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

- *If you forget to use it*

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

- *If you use too much (overdose)*

- Contact your doctor if you have used more than 15g in one day.
- Excessive prolonged use of *Xamiol® Gel* may also cause a problem with calcium in your blood, which usually normalizes 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).

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Xamiol® Gel.*

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give *Xamiol® Gel* to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

- Avoid using under a bathing cap, tight bandages or tight dressings as it increases the absorption of the steroid
- Avoid use on 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.

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 *Xamiol® Gel*

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

Side effects

Like all medicines, *Xamiol® Gel* can cause side effects, although not everybody gets them.

Approximately 1 in 12 people may experience side effects, but most of these are reactions at the site where the gel has been applied.

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 *Xamiol® Gel*
Uncommon (affect less than 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 *Xamiol® 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, or use under occlusion.

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 your 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 taking *Xamiol® 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

DK/H/279/001/IA/032/G - 18 Mar 2011

- 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 taking *Xamiol® Gel*, 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 blood are bone pain, constipation, poor appetite, nausea and vomiting. This can be serious, and you should contact your doctor immediately. However, when the treatment is stopped, the levels return to normal.

If you notice the above or any other changes in your health while taking this medicine, tell your doctor.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of *Xamiol® Gel*

- *Storage*

- Keep out of the reach and sight of children.
- Do not use *Xamiol® Gel* after the expiry date, which is stated on the bottle after EXP. The expiry date refers to the last day of that month
- Do not refrigerate. Keep the bottle in the carton in order to protect from light
- Shelf life of 3 years if left unopened
- Discard the bottle with any remaining gel 3 months after first opening.
- Do not store above 30°C.

- *Disposal*

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.

Product Description

- *What it looks like*

Xamiol® Gel is an almost clear, colourless to slightly off-white gel filled in high-density polyethylene bottles with low-density polyethylene nozzle and a high-density polyethylene screw cap.

The bottles are placed in cartons.
Pack sizes: 15, 30, 60, 2 x 60g and 3 x 60g.
Not all pack sizes may be marketed.

- *Ingredients*
  - Active ingredient(s)
    Calcipotriol and Betamethasone.

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

  - Inactive ingredients:
    - Paraffin, liquid
    - Polypropylene glycol-15 stearyl ether
    - Castor oil, hydrogenated

- *MAL number:*
  MAL10120015A

Manufacturer
LEO Laboratories Ltd
285 Cashel Road Crumlin,
Dublin 12, Ireland.

Product Registration Holder
DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm, No.1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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