

Silkis® 3 micrograms/g

calcitriol

OINTMENT



Package leaflet: Information for the user

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 symptoms 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 **Silkis** is and what it is used for
2. What you need to know before you use **Silkis**
3. How to use **Silkis**
4. Possible side effects
5. How to store **Silkis**
6. Contents of the pack and other information

1. What **Silkis is and what it is used for**

Silkis is used for the topical treatment of mild to moderately severe plaque psoriasis with up to one third of body surface area involvement. It contains an active ingredient, calcitriol (a vitamin D derivative), which inhibits and normalizes the unrestrained cell growth in psoriasis affected skin.

2. What you need to know before you use **Silkis**

Do not use **Silkis:**

- if you are treated by systemic (oral) route for a calcium deficiency
- if you have a kidney or liver disease
- if you have high blood calcium levels or if you suffer from abnormal calcium metabolism
- if you are allergic to calcitriol or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using **Silkis**.

- Carefully apply the ointment to the face, since it has a greater risk of irritation. Avoid contact with the eyes.
- After using the ointment, wash your hands to prevent unintentional spread to non-affected zones.
- Due to a potential effect on calcium metabolism, the ointment may not be applied under an occlusive wound dressing.
- In case of severe irritation or allergic reaction occur, the treatment should be discontinued and the doctor contacted.
- Although no significant hypercalcaemia (high blood calcium levels) was observed during clinical studies with this ointment, there is some absorption of calcitriol by the skin. This gives a risk of an increase of blood or urine calcium levels. This risk is minimal if you follow your doctor's advice.
- 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

There is limited data on the use of **Silkis** in children. Therefore, use in children should be avoided.

Other medicines and **Silkis**

Silkis might interfere with other medicines such as:

- Thiazide diuretics as their use jointly with this medicine would increase your blood calcium levels.
- Medications whose action can be modified by a change in calcium blood level such as digoxin
- Calcium supplements or high doses of vitamin D.
- Peeling agents, astringent agents or irritant agents, because additional irritant effects might occur.

Inform your doctor of any other topical treatment you may have used or you are using for your psoriasis lesions, before starting this treatment.

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 or pharmacist for advice before taking this medicine.

Silkis should not be used if you are breast-feeding.

Driving and using machines:

The treatment does not affect the ability to drive and use machines.

3. How to use **Silkis**

Silkis is an ointment for use on the skin only (cutaneous).

Always use this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Dosage instructions

- First wash and dry the affected areas of your skin.
- Apply a thin layer of **Silkis** over the affected areas to be treated twice a day, morning and evening before retiring, or as advised by your doctor.
- Wash your hands after each application in order to avoid any contact with other non-lesional areas.
- Do not use more than 30 g of ointment per day and do not cover more than one third of your skin area (approximately one full arm and one full leg).

Do not swallow this product. If you accidentally do so, seek immediate medical advice.

Regularly follow your treatment, according strictly to your doctor's instructions.

If you feel that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

If you use more **Silkis than you should:**

- If the product is applied excessively, no more rapid or better results will be obtained and marked redness, peeling or discomfort may occur.
- Always contact your physician to hear whether treatment or discontinuation is necessary if too much **Silkis** is used.
- Hypotonia (decreased tension in muscles), nausea, vomiting, lack of appetite, constipation and depression may occur after using too much calcitriol. Therefore, contact your physician if these symptoms appear.

If you forget to use **Silkis:**

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In case of severe irritation or contact allergy (redness, itching), the treatment should be stopped and the patient should seek medical attention. If contact allergy is confirmed, the treatment should be discontinued.

This medicine may cause some unwanted effects at the site of application:

- **Common (may affect up to 1 in 10 people)**
 - pruritus (itching skin)
 - skin discomfort
 - skin irritation
 - erythema (skin redness)
- **Uncommon (may affect up to 1 in 100 people)**
 - dry skin
 - psoriasis aggravation
- **Not known (frequency cannot be estimated from the available data)**
 - skin oedema
 - contact dermatitis

Galderma Laboratories

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Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Silkis

- Keep out of the sight and reach of children.
- Discard the tube 8 weeks after first opening.
- Do not use this medicine after the expiry date which is stated on the carton after Exp. date. The expiry date refers to the last day of that month.
- No special precautions for storage.

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 to protect the environment.

6. Contents of the pack and other information

What Silkis contains

The active substance is Calcitriol (3 micrograms per g).

The other excipients are liquid paraffin, white soft paraffin and alpha-tocopherol.

What Silkis looks like and contents of the pack

Silkis is a white, translucent ointment.

This ointment is available on prescription from your doctor in tubes containing 15g, 30g or 100g (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder in United Kingdom

Galderma (U.K.) Limited,

Evergreen House North,

Grafton Place,

London, England, NW1 2DX

PL 10590/0047

Marketing Authorisation Holder in Ireland

Galderma International,

Tour Europlaza,

20, Avenue André Prothin,

La Défense 4,

92927 Paris, La Défense, CEDEX,

France

PA 22743/014/1

Manufacturer

Laboratoires Galderma

ZI - Montdésir

74 540 Alby sur Chéran

France

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic: Silkis mast

Germany: SILKIS 3 µg/g Salbe

Spain: SILKIS 3 microgramos/g pomada

Finland: Silkis 3 mikrog/g voide

France: SILKIS 3 microgrammes/g, pommade

Ireland: SILKIS 3 micrograms per g ointment

Italy: SILKIS 3 microgrammi per grammo di unguento

Netherlands: SILKIS, zalf 3 microgram/gram

Norway: Silkis 3 mikrogram per g salve

Portugal: SILKIS 3 microgramas por grama de pomada

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

Ireland

Galderma (UK) Ltd.

Tel: + 44 (0) 1923 208950

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