

Package leaflet: Information for the user

Curatoderm® 4 micrograms/g Lotion

Tacalcitol

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

1. What Curatoderm Lotion is and what it is used for

Curatoderm Lotion contains tacalcitol which is a drug that belongs to a group of medicines called antipsoriatics and is a vitamin D derivative.

Curatoderm Lotion is used to treat a condition known as psoriasis vulgaris especially on the scalp. Psoriasis is a skin disorder in which itchy, red, flaky patches appear on the skin or scalp. Within affected areas of skin, new cells are being produced faster than normal, but old dead cells are only being shed at the normal rate. As live skin cells accumulate, the skin becomes thickened and inflamed. Curatoderm Lotion works by slowing down cell production and bringing it back to normal and helps to reduce inflammation.

2. What you need to know before you use Curatoderm Lotion

Do not use Curatoderm Lotion

- if you are allergic to tacalcitol or any of the other ingredients of this medicine (listed in section 6).
- If you suffer with psoriasis punctata which are individual lesions, each red in colour and tipped with a single white scale.
- If you suffer with psoriasis pustulosa which is inflammation of the skin and small white or yellow pus-filled blisters.
- If you suffer with severe liver, kidney or heart disease.

- if you have ever had problems with too much calcium in your blood (hypercalcaemia or other disorders of calcium metabolism).

If this applies to you, do not use this medicine and speak to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before using Curatoderm Lotion.

When applying Curatoderm Lotion to the face do not allow the lotion to come in contact with the eyes. If it does, rinse thoroughly with water.

Tell your doctor if:

- you have or have had problems with your kidneys,
- you have a particular type of psoriasis called generalized pustular psoriasis or erythrodermic exfoliative psoriasis,
- you are taking high doses of vitamin D (more than 500IU).

Your doctor may want to check the level of calcium in your blood if you have any of these conditions.

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.

Other medicines and Curatoderm Lotion

Tell your doctor or pharmacist if you are taking or using, have recently taken or used or might take or use any other medicines, including medicines obtained without a prescription.

Especially:

- Multivitamin products or vitamin D
- Other treatments for psoriasis

If you are receiving ultraviolet (UV) therapy, this should be given in the morning and Curatoderm Lotion used at bedtime.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

The potential risk to the baby if Curatoderm Lotion is used during pregnancy is unknown. Therefore treatment with Curatoderm Lotion during pregnancy should be avoided.

It is not known if Curatoderm Lotion passes into breast milk. Therefore treatment with Curatoderm Lotion whilst breastfeeding is not recommended.

Driving and using machines

No particular precautions are required.

Curatoderm Lotion contains propylene glycol and dodecyl gallate

This medicine contains 100 mg propylene glycol and 0.2 mg dodecyl gallate in each gram.

Due to its propylene glycol content this medicine may cause skin irritation. It may also induce slight irritation to the skin, eyes and mucous membranes due to its dodecyl gallate content.

3. How to use Curatoderm Lotion

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

Use in children

Curatoderm Lotion is not recommended for use in children, as there is limited experience.

Curatoderm Lotion is for use by adults including the elderly.

Curatoderm Lotion can be used on all areas of the body including face, hairline, scalp, armpits, elbows and knees.

Follow your doctor's instructions for use exactly. The following are general guidelines:

- Apply Curatoderm Lotion once a day, preferably at bedtime.
- Do not use more than 10ml of lotion (equivalent to 2 teaspoons) each day.
- Spread the lotion over the areas of skin affected by psoriasis and then rub it in.
- To treat the scalp, part your hair and place the nozzle close to the affected area, apply a few drops, then rub the lotion in gently.
- Avoid transfer of the lotion to other areas of the body not affected by psoriasis.
- Avoid contact with the eyes. When Curatoderm Lotion accidentally comes into contact with your eyes, rinse them thoroughly with water
- Wash your hands as soon as you have finished applying the lotion.

Duration of treatment

- Your doctor will tell you for how long you need to use the lotion.

If you also use Curatoderm Ointment

- Curatoderm is also available as an ointment. If you are also using Curatoderm Ointment, take into account that the quantity of applied tacalcitol adds up. You should not use more than 280 micrograms of tacalcitol per week. That is for example equivalent to 30ml Curatoderm Lotion plus 40g Curatoderm Ointment per week.

If you use more Curatoderm Lotion than you should

If you have used too much Curatoderm Lotion, tell your doctor as it may be necessary to check the amount of calcium in your blood.

If you forget to use Curatoderm Lotion

If you forget to use Curatoderm Lotion at the usual time, use it as soon as you remember, then carry on as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Rarely (may affect up to 1 in 1,000 people)

Local skin reactions such as itching, burning or redness may be experienced. These are usually mild effects and don't last very long.

Contact dermatitis or a worsening of the skin condition may occur.

The following side effects have also been reported (frequency not known, cannot be estimated from the available data)

Elevated calcium levels in the blood (hypercalcaemia).

Hypersensitivity reactions (including swelling, oedema and face oedema).

Rash (erythematous, macular, papular, vesicular).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Curatoderm Lotion

Keep this medicine out of the sight and reach of children.

Keep the bottle in the outer carton in order to protect it from light.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Do not use for longer than 6 months after first opening the container, write the date of first opening the container bottle on the carton label.

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 Curatoderm Lotion contains

- The active substance is tacalcitol.
1 g of lotion contains 4 micrograms of tacalcitol (as monohydrate).
- The other ingredients are purified water, light liquid paraffin, medium-chain triglycerides, propylene glycol, octyldodecanol, macrogol (21) stearylether, diisopropyl adipate, phenoxyethanol, disodium phosphate dodecahydrate, xanthan gum, potassium dihydrogen phosphate, disodium edetate, dodecyl gallate.

What Curatoderm Lotion looks like and contents of the pack

Curatoderm Lotion is a white, thin emulsion for use on the skin

Your medicinal product comes in either 20 ml, 30 ml or 50 ml HDPE plastic bottle and with HDPE screw cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Almirall Hermal GmbH
Scholtzstrasse 3, 21465 Reinbek, Germany
Tel: +49-40/72704-0
Fax: +49-40/7229296
info@almirall.de

This leaflet was last revised in 11/2021