

## **Package leaflet: Information for the user**

### **Curatoderm® 4 micrograms/g Ointment**

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

#### **1. What Curatoderm Ointment is and what it is used for**

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

Curatoderm Ointment is used to treat a condition known as psoriasis vulgaris. 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 Ointment works by slowing down cell production and bringing it back to normal and helps reduce inflammation.

#### **2. What you need to know before you use Curatoderm Ointment**

##### **Do not use Curatoderm Ointment**

- if you are allergic to tacalcitol or any of the other ingredients of this medicine (listed in section 6).
- 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.

## **Take special care with Curatoderm Ointment**

When applying Curatoderm Ointment to the face: Do not allow the Ointment to come in contact with the eyes. If it does, rinse thoroughly with water.

### **Warnings and precautions**

Talk to your doctor before using Curatoderm Ointment 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.

### **Children and adolescents**

The safety and efficacy of Curatoderm Ointment in children and adolescents under 18 years have not been established.

### **Other medicines and Curatoderm Ointment**

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

Especially:

- Multivitamin products or vitamin D

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

### **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 using this medicine.

The potential risk to the baby if Curatoderm Ointment is used during pregnancy is unknown. Therefore if you are pregnant or likely to become pregnant whilst using Curatoderm Ointment make sure your doctor knows.

It is not known if Curatoderm Ointment passes into breast milk. Only a small amount is absorbed into the body after skin treatment. It is probably not necessary to stop breast-feeding during treatment.

If the breast area is affected by psoriasis, it is recommended that the breast area is not treated with Curatoderm Ointment or breast-feeding should be stopped. Discuss this with your doctor.

### **Driving and using machines**

Curatoderm Ointment is not expected to have any effect on your ability to drive or use machines.

**Curatoderm contains butylhydroxytoluene (E 321) contained in the excipient Paraffin, white soft.** Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

### **3. How to use Curatoderm Ointment**

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

#### **Use in children**

Curatoderm Ointment is not recommended for use in children, as there is limited experience. Curatoderm Ointment is for use by adults including the elderly.

Curatoderm Ointment 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 Ointment once a day, preferably at bedtime.
- Don't use more than 10 grams of ointment (about the size of a chestnut) each day.
- Spread the ointment thinly over the areas of skin affected by psoriasis.
- If you are using the ointment on your scalp it can be shampooed out the next morning.
- Avoid transfer of the ointment to other areas of your body not affected by psoriasis.
- Wash your hands as soon as you have finished using the ointment.

#### **Duration of treatment**

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

#### **If you also use Curatoderm Lotion**

- Curatoderm is also available as a lotion. If you are using Curatoderm Lotion, take into the 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 40g Curatoderm Ointment plus 30ml Curatoderm Lotion per week.

#### **If you use more Curatoderm Ointment than you should**

It is important to tell your doctor if you have used too much Curatoderm Ointment, as it may be necessary to check the amount of calcium in your blood.

#### **If you forget to use Curatoderm Ointment**

If you forget to use Curatoderm Ointment at the usual time, use it as soon as you remember, then carry on as before. Do not apply two doses at the same time.

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.

- Local skin reactions such as itching, burning or redness may be experienced.
- Sometimes the ointment makes your skin redder and more irritated for a short time after you have applied it.
- On rare occasions, mild contact dermatitis or a worsening of the skin condition may occur.

These are usually mild effects and don't last very long.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.mhra.gov.uk/yellowcard](http://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 Ointment**

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

Curatoderm Ointment should be stored below 30°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 tube.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. Contents of the pack and other information**

##### **What Curatoderm Ointment contains**

The active substance is tacalcitol

There are 4 micrograms of tacalcitol (the active ingredient) in each gram of ointment

The other ingredients are paraffin, white soft (contains butylhydroxytoluene E321), liquid paraffin and diisopropyl adipate.

##### **What Curatoderm Ointment looks like and contents of the pack**

Curatoderm Ointment is a translucent and white, glossy ointment.  
Your medicinal product comes in either 5g, 20g, 30g or 100g aluminium tubes with a screw cap.  
Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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