

# ELIDEL®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using ELIDEL?

ELIDEL contains the active ingredient pimecrolimus. ELIDEL is used to treat the early signs and symptoms of eczema such as itching, redness and tiny bumps or thickening of the skin in infants of 3 months or older, children, teenagers and adults.

For more information, see Section [1. Why am I using ELIDEL?](#) in the full CMI.

### 2. What should I know before I use ELIDEL?

Do not use if you have ever had an allergic reaction to pimecrolimus or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ELIDEL?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ELIDEL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ELIDEL?

- Apply a thin layer of the cream to the affected skin twice daily for as long as your doctor tells you to.
- Do not cover the treated skin with occlusive dressings. However, you can wear normal clothing.

More instructions can be found in Section [4. How do I use ELIDEL?](#) in the full CMI.

### 5. What should I know while using ELIDEL?

#### Things you should do

- Remind any doctor and pharmacist you visit that you are using ELIDEL.
- Tell your doctor if you become pregnant while you are using this medicine.

	<ul style="list-style-type: none"> <li>• Tell your doctor if you develop lumps/painful sores anywhere in your body, or develop any moles/skin infection, or you notice changes in existing moles.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not use this medicine continuously for long periods without interruption.</li> <li>• Avoid exposure to the sun of skin areas treated with ELIDEL. Do not use a sunlamp or tanning table.</li> <li>• Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you experience facial flushing or skin irritation when you drink alcohol during treatment with ELIDEL.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store the tube of cream in the outer carton in a cool dry place below 25°C. Once you have</li> </ul>

opened the tube of cream, you should use it for no more than 12 weeks.

- Do not store ELIDEL in the bathroom or near a sink. Do not leave it in the car or on window sills.

For more information, see Section [5. What should I know while using ELIDEL?](#) in the full CMI.

## 6. Are there any side effects?

**Tell your doctor if you experience any of the following and they worry you or tell your doctor immediately if any of the following symptoms are severe:** a temporary feeling of warmth and/or burning, irritation, itching or reddening, rash, pain, feeling of prickling, dryness, flaking, swelling, folliculitis, cold sores, genital herpes, shingles, eczema herpeticum, any other signs or symptoms that are different from your usual symptoms of eczema (may be signs of a skin infection), a new spot, freckle or mole or a change to an existing one, change of skin colour and swelling of lymph nodes. **Tell your doctor immediately, or go to the Emergency Department at your nearest hospital, if any of the following happen:** sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ELIDEL®

**Active ingredient:** *pimecrolimus*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ELIDEL. This leaflet has mostly been written for patients who are using ELIDEL on themselves, but, as ELIDEL can be used in children as young as 3 months, the same advice and precautions need to be exercised when parents and carers are using ELIDEL on children who have been prescribed the product. There are additional instructions when using ELIDEL in infants up to 2 years and these are explained separately in the leaflet.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ELIDEL.**

**Where to find information in this leaflet:**

- [1. Why am I using ELIDEL?](#)
- [2. What should I know before I use ELIDEL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ELIDEL?](#)
- [5. What should I know while using ELIDEL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using ELIDEL?**

**ELIDEL contains the active ingredient pimecrolimus.**

**ELIDEL is used to treat the early signs and symptoms of eczema (also called atopic dermatitis), such as itching, redness and tiny bumps or thickening of the skin. It is suitable for infants of 3 months or older, children, teenagers and adults.**

ELIDEL can be used to treat repeated episodes of eczema. Treatment is started as soon as the first symptoms of eczema appear, to prevent these from progressing to more severe symptoms that may require the use of a steroid cream.

However, if a steroid cream is required to treat an episode of eczema, ELIDEL should be stopped and restarted to treat any remaining symptoms after the steroid cream has been stopped.

ELIDEL is a steroid-free medicine that treats inflammation of the skin. It works in specific cells in the skin that cause inflammation and the characteristic redness and itching of eczema.

Ask your doctor if you have any questions about why this medicine has been prescribed.

Your doctor may have prescribed it for another purpose.

## **2. What should I know before I use ELIDEL?**

### **Warnings**

#### **Do not use ELIDEL if:**

- you are allergic to pimecrolimus, (the active ingredient), macrolactams (drugs similar to pimecrolimus) or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are having light therapy (called phototherapy) for your skin condition.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

#### **Before you start to use it**

**If you want more information, discuss this with your doctor.**

Pimecrolimus is absorbed in small amounts through the skin. A very small number of people who have used ELIDEL have developed skin cancer or lymphoma, but a link that ELIDEL caused these cancers has not been shown. The number of cases reported is small, and so far is lower than the average in the general population. Although it cannot be excluded, it is unlikely that people using ELIDEL cream have an increased chance of getting these conditions. It is important that ELIDEL

should only be used as directed by your doctor. Only apply it to the places your doctor has said it should go. Use it only for as long as directed.

## **Check with your doctor if you have:**

- had skin cancers removed or you have changes in your skin (called pre-malignant or pre-cancerous changes) that may develop into skin cancer
- swelling of the lymph nodes - the bean-shaped organs found in the underarm, groin, neck, chest and abdomen that act as filters for the lymph fluid as it circulates through the body
- an infection of the skin
- generalised erythroderma (a skin disorder characterised by reddening and scaling of most of the skin)
- Netherton syndrome (a rare hereditary disorder)
- weakened immune system (for example as a result of medical conditions such as HIV, diabetes, cancer, or from taking medicines that suppress immunity).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant. There is not enough information to recommend the use of this medicine during pregnancy.

Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Although the amount of pimecrolimus that is absorbed into your blood stream is very low, it is not known if it passes into the breast milk and could affect your baby. Your doctor can discuss with you the benefits and risks involved with using this medicine while you are breastfeeding.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Although it is unlikely that other medicines and ELIDEL will interfere with each other, you should always make sure your doctor knows what medicines you are taking, especially any other creams or ointments you are using on your skin.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ELIDEL.**

### **4. How do I use ELIDEL?**

#### **Areas of skin to avoid**

- **Do not use the cream:**

- inside your nose, eyes or mouth. Do not swallow it.
- on areas of the skin affected by active viral infection such as cold sores or chicken pox.
- if your skin is infected, check with your doctor before using ELIDEL. Your doctor may ask you to use another medicine to clear the infection first.
- on your breasts while you are breastfeeding.
- if you have had a vaccination recently, do not apply the cream to the site of vaccination until reddening of the skin and/or swelling disappears.

**If you accidentally applied the cream to any of these areas, wipe it off and rinse well with clean water.**

## **How much to use**

- **Follow all directions given to you by your doctor and pharmacist carefully.** These instructions may differ from the information contained in this leaflet.
- **If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**
- **To prevent the early symptoms of eczema from progressing to more severe symptoms, apply the cream twice daily, for instance once in the morning and once in the evening.**

## **How to use it**

Apply the cream as follows:

1. Wash and dry your hands.

2. Open the tube. The first time you use the tube you will need to break the seal using the spike in the top of the cap.
3. Squeeze cream onto your finger.
4. Apply a thin layer of cream and completely cover the affected skin.
5. Rub in gently and completely.
6. Replace the cap on the tube.
7. Wash your hands after applying the cream.

Do not cover the skin being treated with occlusive dressings. However, you can wear normal clothing.

## **Using other skin products together with ELIDEL**

ELIDEL is often used at the same time as other skin products, such as emollients (moisturisers) and sunscreens.

**If you are going to apply another product to your skin (such as a moisturiser or sunscreen) in addition to ELIDEL, wait until the first one is completely absorbed into your skin without any residue before you apply the next one.**

If you want to use a moisturiser, you can apply it after using ELIDEL.

If you are going to be outside, wear protective clothing and use at least a 15+ low-irritant sunscreen.

## **When to use ELIDEL**

ELIDEL should be used twice daily, once in the morning and once in the evening.

## **How long to use it**

For each episode of eczema, begin using ELIDEL as soon as you notice the first signs and symptoms and until the end of redness when you should stop treatment. Continue using the cream for as long as your doctor tells you to.

**In infants up to 2 years of age:** treatment of each episode of eczema should usually last no more than 3 weeks.

**Older children, teenagers and adults:** treatment can generally continue of each episode of eczema for up to 6 weeks, if necessary, to clear up their signs and symptoms.

**If signs and symptoms come back, you should start treatment again.**

**If there is no improvement after 6 weeks of treatment or your condition worsens, tell your doctor.**

In that case it may be necessary to stop using the cream while your doctor re-evaluates your condition.

**Do not use this medicine continuously for long periods without interruption.**

## **If you forget to use ELIDEL**

If you forget to apply the cream, apply it as soon as possible and then continue your normal routine.

## **If you use too much ELIDEL**

**If you accidentally apply more cream to your skin than you were told to, just wipe it off. It will not harm you.**

**If you or anyone else swallows some of the cream:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using ELIDEL?**

### **Things you should do**

**Avoid exposure to the sun of skin areas treated with ELIDEL. Do not use a sunlamp or tanning table. When you are outdoors, wear protective clothing and use at least a 15+ low-irritant sunscreen.**

**Tell your doctor if you:**

- **become pregnant while you are using this medicine.**

Your doctor can discuss with you the risks of using it while you are pregnant.

- **develop lumps anywhere in your body, or develop any moles, or you notice changes in existing moles.**
- **think you may have developed a skin infection or notice painful sores anywhere on your body while you are using ELIDEL.**
- **notice the signs and symptoms of your eczema seem to be getting worse**
- **are about to be started on any new medicine or given a vaccination. Remind your doctor and pharmacist that you are using ELIDEL.**

**Tell any other doctor or pharmacist who treats you that you are using ELIDEL.**

## **Things you should not do**

- Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.
- Do not use it to treat any other complaints unless your doctor tells you to.

## **Drinking alcohol**

**Tell your doctor if you experience facial flushing or skin irritation when you drink alcohol during treatment with ELIDEL.** Rarely, facial flushing or skin irritation (e.g. rash, burning, itching or swelling) can

occur in people who drink alcohol while they are using ELIDEL.

## **Looking after your medicine**

- Store the tube of cream in the outer carton in a cool dry place below 25°C. Ensure the cap is tightly closed.
- Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.
- Heat and dampness can destroy some medicines. ELIDEL will keep well if it is cool and dry.

**Keep it where young children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **When to discard your medicine**

**Once you have opened the tube of cream, you should use it for no more than 12 weeks.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.** See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• a temporary feeling of warmth and/or burning</li><li>• irritation, itching or reddening</li><li>• rash, pain, feeling of prickling, dryness, flaking, swelling</li><li>• folliculitis (inflammation of the hair follicles, sometimes causing pustules)</li><li>• blisters around the lips, nose or chin (cold sores)</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>If any of these symptoms are severe, tell your doctor immediately.</b></p> <p>Most of these symptoms happen early in treatment, are not usually severe and do not last long.</p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● blisters, cracks, pain or swelling around the groin (genital herpes)</li> <li>● painful, red skin rash or blister-like sores (shingles)</li> <li>● clusters of itchy or painful blisters around the face or neck (eczema herpeticum)</li> <li>● any other signs or symptoms that are different from your usual symptoms of eczema. These may be signs of a skin infection.</li> <li>● a new spot, freckle or mole or a change to an existing one</li> <li>● a change of skin colour.</li> <li>● a swelling of your lymph nodes while using ELIDEL. Lymph nodes are the bean-shaped organs found in the underarm, groin, neck, chest and abdomen that act as filters for the lymph fluid as it</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
circulates through the body.	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What ELIDEL contains**

<b>Active ingredient (main ingredient)</b>	Each gram of ELIDEL 1% cream contains 10 mg pimecrolimus.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● benzyl alcohol</li><li>● cetyl alcohol</li><li>● citric acid</li><li>● mono- and di-glycerides</li><li>● oleyl alcohol</li><li>● propylene glycol</li><li>● sodium cetostearyl sulfate</li><li>● sodium hydroxide</li><li>● stearyl alcohol</li><li>● medium chain triglycerides</li><li>● purified water</li></ul>

<b>Potential allergens</b>	benzyl alcohol as a preservative
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What ELIDEL looks like**

ELIDEL is a whitish, odourless, non-staining and easily spreadable cream packaged in an aluminium tube with a screw cap. Tubes of 15 g and 30 g are available (AUST R 93680).

## **Who distributes ELIDEL**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

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