

Elidel(R)

pimecrolimus

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Elidel cream.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks to you or your child of using Elidel cream against the benefits they expect it will provide.

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.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Elidel cream is used for

Elidel cream 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 cream can be used to treat any remaining symptoms after the steroid cream has been stopped.

Elidel cream 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.

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

Before you use Elidel cream

When you must not use it

Do not use Elidel cream if you have ever had an allergic reaction to pimecrolimus (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to a medicine may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Elidel cream if 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

Below is some information on the effects of Elidel when given to animals in large doses by mouth over long periods of time.

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

Some laboratory animals given large doses of pimecrolimus by mouth for long periods of time developed lymphomas. Elidel cream is absorbed in small amounts through the skin when given to people. There

have been isolated reports of lymphoma and/or skin cancer in people who were using Elidel cream, but no causal link has yet been shown between Elidel cream use and the development of these conditions. The number of cases reported is small and so far is lower than the average in the general population. Although it can not 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 and only for as long as directed. Only apply it to the places your doctor has said it should go. Use it only for as long as directed.

Tell your doctor if you have any of the following medical problems/ conditions:

- * 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
- * you have 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
- * you have 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)
- * impaired immune system (for example as a result of medical conditions such as HIV, diabetes or cancer)

Tell your doctor if you are pregnant or planning 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.

Tell your doctor if you are breast-feeding.

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 breast-feeding.

Taking other medicines

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

Although it is unlikely that other medicines and Elidel cream 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.

If you have not told your doctor about any of these things, tell him/her before you start using this medicine.

How to use Elidel cream

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.

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

- * on your breasts while you are breast-feeding.
- * 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 to use it

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.

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.

Using other skin products together with Elidel

Elidel cream 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 cream, 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 cream. However, after a bath or shower, apply the moisturiser first before applying the cream.

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

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 it

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

If you have too much (Overdose)

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, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, even if there are no signs of discomfort or poisoning.

While you are using Elidel cream

Things you must do

If you become pregnant while you are using this medicine, tell your doctor.

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

If you develop lumps anywhere in your body, or develop any moles, or you notice changes in existing moles, tell your doctor.

These may be signs of the development of skin cancer or lymphoma. There have been isolated reports of these conditions while using Elidel cream but no causal link has been shown between Elidel cream use and the development of these conditions.

If you think you may have developed a skin infection while you are using Elidel cream, see your doctor right away.

If your skin is infected, your doctor will prescribe another medicine to treat the infection in addition to Elidel cream. If the infection does not go away, your doctor may ask you to stop using Elidel cream until the infection has been cleared up.

If you experience facial flushing or skin irritation when you drink alcohol during treatment with Elidel cream, tell your doctor.

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 Cream.

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

If the signs and symptoms of your eczema seem to be getting worse, tell your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Elidel cream.

Tell any other doctor or pharmacist who treats you that you are using Elidel cream.

Things you must 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Elidel cream.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

If you notice any of the following symptoms on the skin where you have applied the cream and you are worried about them, tell your doctor:

- * a temporary feeling of warmth and/or burning
- * irritation, itching or reddening
- * rash, pain, feeling of prickling, dryness, flaking, swelling
- * folliculitis (inflammation of the hair follicles, sometimes causing pustules)
- * any other signs or symptoms that are different from your usual symptoms of eczema. These may be signs of a skin infection.
- * a new spot, freckle or mole or a change to an existing one

- * a change of skin colour.

Tell your doctor if you notice 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 circulates through the body.

If any of the above symptoms are severe, tell your doctor immediately.

Most of these symptoms happen early in treatment, are not usually severe and do not last long.

If any of the following happen, stop taking Elidel and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- * 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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Other side effects not listed here or not yet known may happen in some people.

After using Elidel cream

Storage

- * Store the tube of cream in the outer carton. Make sure the cap is tightly closed.
- * Store it in a cool dry place below 25 degrees C. (room temperature).
- * Once you have opened the tube of cream, you should use it for no more than 12 weeks.
- * 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 cream will keep well if it is cool and dry.

Keep the medicine 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.

Disposal

If you no longer need the cream or it has passed its expiry date, return any unused medicine to your pharmacist.

Product description

What it looks like

Elidel cream is a whitish, odourless, non-staining and easily spreadable cream packaged in an aluminium tube with a screw cap; in tubes of 15 and 30 grams.

Ingredients

Each gram of Elidel 1% cream contains 10 mg of the active ingredient, pimecrolimus. Elidel cream also contains the following inactive ingredients:

- * benzyl alcohol
- * cetyl alcohol
- * citric acid - anhydrous
- * glyceryl monostearate
- * oleyl alcohol
- * propylene glycol
- * sodium cetostearyl sulfate
- * sodium hydroxide
- * stearyl alcohol
- * medium chain triglycerides
- * water - purified.

Sponsor

Elidel cream is supplied in Australia by:
NOVARTIS Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone 1 800 671 203

Web site: www.novartis.com.au

(R) = Registered Trademark

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