

Elidel®

Pimecrolimus

1% Cream

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Elidel cream against the benefits they expect it will give you.

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.

Elidel belongs to a group of medicines called topical calcineurin inhibitors

How to use Elidel cream

Do not use the cream:

- inside your nose or mouth. Do not swallow it.
- in your eyes. If the cream accidentally gets into your eyes, wipe it away and rinse the eyes well with clean water.
- on areas of the skin affected by active viral infection such as cold sores
- on broken skin
- on your breasts while you are breast-feeding.
- continuously for a long time, as the safety of using Elidel for a long period of time is not known.
- In areas of potentially malignant or pre-malignant skin lesions.

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.

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:

- Wash and dry your hands.

- 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.
- Squeeze cream onto your finger.
- Apply a thin layer of cream and completely cover the affected skin.
- Rub in gently and completely.
- Replace the cap on the tube.

If you wish, you can apply a moisturiser immediately after using Elidel cream. However, after a bath or shower, apply the moisturiser first before applying the cream.

How long to use it

For the intermittent long-term treatment of eczema, begin using Elidel as soon as you notice the first signs and symptoms, and continue using for up to 6 weeks. If you have not noticed any signs of improvement, Elidel should be stopped and you should consult your doctor.

Use in infants (3-23 months of age) should be limited to the smallest practicable body surface area and treatment should generally be limited to no more than 3 weeks.

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 the

National Poisons Information Centre, Dunedin (0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department 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 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.

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+ sunscreen. Wait until Elidel cream is completely absorbed into your skin without any residue before you apply the sunscreen.

Take special care if you have a skin disease called Netherton's syndrome or generalised erythroderma (inflammatory reddening of the entire skin). Your doctor will have told you if you have this.

Take special care if you have been told you have a weak immune system

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.

In rare instances, people may be allergic to Elidel 1% cream. This could cause swelling and pain, skin rashes or hives. In very rare cases, the allergic reactions can be severe with symptoms like sudden wheezing and chest pain or tightening, swelling of eyelids, face or lips.

If you experience any of these symptoms soon after using Elidel cream, stop using the cream and tell your doctor or pharmacist immediately.

Tell your doctor if your lymph nodes become swollen during treatment with Elidel

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.
- in rare cases, application site reactions can be severe.
- rarely, facial flushing or skin irritations (e.g. rash, burning, itching or swelling) can occur in patients who drink alcohol while using Elidel 1% cream.

In rare cases, patients have had cancer (e.g. skin or lymphoma) during treatment with topical calcineurin inhibitors, including Elidel cream.

However a causal link has not been shown.

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.

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

Some people may get other side effects of Elidel cream.

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 months.
- 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 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 New Zealand by:
 NOVARTIS New Zealand Limited
 Novartis New Zealand Limited
 Private Bag 65904
 Mairangi Bay
 Auckland
 Building G, 5 Orbit Drive
 Rosedale
 Auckland 0632
 Telephone: 0800 652 422
 ® = Registered Trademark

This leaflet was prepared on 23 June 2009 based on the currently approved data sheet for Elidel