douglas
improving lives

Consumer Medicine Information

Zematop®

Tacrolimus

0.1% w/w ointment

What is in this leaflet

Please read this leaflet carefully before you start using Zematop.

This leaflet answers some common questions about Zematop. 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 Zematop against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Zematop is used for

Zematop belongs to a group of medicines called macrolides. The active ingredient, tacrolimus monohydrate, is an immunomodulating agent.

Zematop is used for the treatment of moderate to severe atopic dermatitis in adults and adolescents over the age of 16 years who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids.

In atopic dermatitis, an over-reaction of the skin's immune system causes skin inflammation (itchiness, redness, dryness). Tacrolimus alters the abnormal immune response and relieves the skin inflammation and the itch.

Once moderate to severe atopic dermatitis is cleared or almost cleared after up to 6 weeks treatment of a flare, and if you are experiencing frequent flares (i.e. 4 or more per year), it may be possible to prevent flares coming back or prolong the time you are free from flares by using Zematop twice weekly.

Your doctor may have prescribed Zematop for another reason.

Ask your doctor if you have any questions about why Zematop has been prescribed for you.

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

Before you use Zematop

When you must not use it

Do not use Zematop if you have an allergy to:

- any medicine containing tacrolimus or a class of medicines called macrolides (e.g. azithromycin, clarithromycin, erythromycin).
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath.
- swelling of the face, tongue, lips, or other parts of the body.
- hives on the skin, rash, or itching.

Do not use Zematop if you have:

- Hypersensitivity to tacrolimus.
- Hypersensitivity to macrolides in general.
- Hypersensitivity to any of the excipients listed at the end of this leaflet.

Do not use this medicine on a child under the age of 16 years. Safety and effectiveness in children younger than 16 years have not been established.

Do not use it after the expiry date (EXP) printed on the back. If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Zematop, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. **you notice any changes different from previous eczema within a treated area.**

2. **you have, or you suspect you may have any form of skin cancer.**

3. **you have allergies to:**
   - Any other medicines including macrolides.
   - Any other substances, such as foods, preservatives or dyes.

4. **you have, or have had, the following medical conditions:**
   - Swollen lymph nodes.
   - Inherited skin barrier diseases (such as Netherton's syndrome).
   - Lamellar ichthyosis (extensive scaling of the skin due to a thickening of the outer layer of the skin).
   - Generalized erythroderma (inflammatory reddening and scaling of the entire skin).
   - Cutaneous Graft Versus Host Disease (an immune reaction of the skin which is a common complication in patients who have undergone a bone marrow transplant).
   - Any other skin barrier defect that may increase systemic absorption of tacrolimus.
   - Liver failure.
   - Congenital or acquired immunodeficiency.
   - Any skin infections.

5. **you are receiving therapy that causes immunosuppression.** You may be at an increased risk of developing certain forms of cancer if Zematop is used in conjunction with your therapy.

6. **you are pregnant or intend to become pregnant.** Your doctor can discuss with you the risks and benefits involved.

7. **you are breastfeeding or planning to breastfeed.** It is known tacrolimus passes into breastmilk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start using Zematop.

Do not give Zematop to a child or adolescent under the age of 16 years. There is no experience with its use in children or adolescents under 16 years old or in infants

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are using Zematop.

It is not known whether topically administered tacrolimus ointment interacts with other topically administered medications.

The possibility of interaction with other known CYP3A4 inhibitors from systemic absorption can not be ruled out. These inhibitors include, but are not limited to:

- erythromycin
- itraconazole

- ketoconazole
- diltiazem

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Zematop.

How to use Zematop

How much to use

Zematop should be applied as a thin layer to affected areas of the skin.

Zematop treatment will be started by your doctor.

Follow all directions given to you by your doctor carefully.

If you do not understand the instructions given to you, ask your doctor or pharmacist for help.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

If you use the wrong dose, Zematop may not work as well and your problem may not improve.

How to use it

Zematop may be used on any part of the body, except on mucous membranes (for example, on the inside of your nose or mouth) or in your eyes.

Zematop should not be applied under dressings (i.e. bandages, wraps, plasters).

When to use it

For Flare Treatment

Treatment should be started with Zematop twice daily until the affected lesion(s) have cleared.

If symptoms recur, twice daily treatment with Zematop should be restarted.

For Maintenance

Your doctor will determine whether it is suitable for you to begin maintenance treatment. Zematop should be used once a day, twice weekly to affected areas to prevent flares. There should be 2-3 days without Zematop treatment between each application.

Use Zematop at about the same time each day.

How long to use it

Zematop can be used in the short-term and intermittently long-term. Zematop should not be used continuously on a long-term basis.

For Flare Treatment

Improvement is generally seen within one week of starting treatment. If no signs of improvement are seen after two weeks of treatment, further treatment options should be discussed with your doctor.

For Maintenance

Your doctor will review your condition after 12 months and determine whether to continue maintenance treatment.

If you forget to use it

If you forget to use Zematop at the scheduled time, do it as soon as you remember and then continue as before.

If you have any further questions about the use of Zematop, ask your doctor or pharmacist.

While you are using Zematop

Things you must do

Make sure that you wash your hands thoroughly after application of Zematop if the hands are not the site for treatment.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Zematop.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If you are outdoors, wear protective clothing and use a SPF 30+ sunscreen. This medicine may cause your skin to be much more sensitive to sunlight than normal. Use of ultraviolet (UV) light from a solarium, therapy with UVB or UVA in combination with psolarens (PUVA) should be avoided during use of Zematop.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

If you become pregnant while using this medicine, discontinue use and tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Zematop to anyone else, even if they have the same condition as you.

Other creams and ointments should not be used in the same area for 2 hours before and 2 hours following Zematop use.

Avoid contact with eyes and mucous membranes (for example, inside of your nose or mouth). If contact occurs, the affected area should be thoroughly wiped to remove Zematop and/or area rinsed with water.

Do not use Zematop under dressings (i.e. bandages, wraps, plasters).

Things to be careful of

Zematop should not affect your ability to drive or use machines.

Tacrolimus has commonly resulted in increased alcohol intolerance. Drinking alcohol while using Zematop may cause the skin or face to become flushed or red and feel hot. It is recommended that alcohol be limited or not used at all while using Zematop.

Use of tacrolimus ointment has been associated with cases of malignancies (for example, lymphoma including skin lymphoma and other skin cancers) in a very small number of people. However, a link to tacrolimus ointment treatment has not been confirmed or refuted on the available evidence so far. **Keep all of your doctor's appointments so that you can be monitored.**

In case of overdose

If you use too much (overdose)

It is unlikely overdose will occur with topical administration.

If ingested, do not attempt to induce vomiting.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have ingested Zematop.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

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 adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Acne
- Folliculitis
- Cold sores
- Conjunctivitis
- Itchy skin
- Increased skin sensitivity
- "Pins and needles" sensation
- Burning sensation
- Discolouration of the skin
- Irritation at the application site

Tell your doctor as soon as possible if you notice any of the following symptoms:

- Swelling or pain at the application site
- Warmth at the application site
- Rash at the application site
- Any other changes to your skin at the application site.

These may be serious side effects of Zematop. You may need urgent medical attention. Serious side effects are uncommon.

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

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Swelling at the application site
- Hives
- Fainting

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Zematop. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After using Zematop

Storage

Keep your ointment in a cool dry place where the temperature stays at or below 25°C.

Do not store Zematop in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

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

Medicines should not be kept indefinitely. Once past their expiry date, medicines should be disposed of.

Disposal

If your doctor tells you to stop using this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

A white to slightly yellowish ointment containing 0.1% w/w tacrolimus in a 10 g, 30 g or 60 g laminated aluminium tube. Not all pack sizes may be available.

Ingredients

Active ingredient(s):

- 1 g of Zematop contains 0.1 mg of tacrolimus as tacrolimus monohydrate.

Inactive ingredients:

- white soft paraffin
- paraffin (liquid)
- propylene carbonate
- beeswax (white)
- paraffin (hard)

Sponsor details

Zematop is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand

Phone: (09) 835 0660

Date of preparation

28 April 2021
(based on data sheet dated 08 April 2021)