

Zematane*

alitretinoin

10 mg and 30 mg capsules

What is in this leaflet

Please read this leaflet carefully before you start taking Zematane.

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

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

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

What Zematane is used for

Zematane is used to treat adults with severe chronic hand eczema that has not got better after topical treatments with steroids.

The active substance in Zematane is alitretinoin. It belongs to a group of medicines known as retinoids which are related to Vitamin A.

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

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

Before you take Zematane

When you must not take it

Do not take Zematane if you have an allergy to:

- any medicine containing alitretinoin or a class of medicines called retinoids.
- 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 take Zematane:

- if you have liver disease
- if you have severe kidney disease
- if you have high blood fats (such as high cholesterol or raised triglycerides).
- if you have uncontrolled thyroid disease.
- if you have very high levels of vitamin A in your body (hypervitaminosis A)
- if you are allergic to alitretinoin, to other retinoids (such as isotretinoin) or any of the other ingredients of this medicine.
- if you are allergic to peanut, soya or have a rare hereditary fructose intolerance should not take this medicine. Zematane contains soya oil and sorbitol.
- if you are taking tetracycline (a type of antibiotic)

Do not take this medicine if you are pregnant.

This medicine can seriously harm an unborn baby.

Do not breastfeed if you are taking this medicine.

The active ingredient in Zematane is likely to pass into your breast milk and may harm your baby.

Do not give this medicine to a child under the age of 18 years old.

Safety and effectiveness in children younger than 18 years have not been established.

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

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

If you are not sure whether you should start taking Zematane, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. you are pregnant or intend to become pregnant.

This medicine can seriously harm an unborn baby (the medicine is said to be “teratogenic”). It can cause serious abnormalities of the unborn baby’s brain, face, ear, eye, heart and certain glands. It also makes a miscarriage more likely. This may happen even if alitretinoin is taken only for a short time during pregnancy. You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed Zematane under strict rules. This is because of the risk of serious harm to the unborn baby. These may include:

- Your doctor has explained the risk of harm to the unborn baby - you must understand why you must not get pregnant and what you need to do to prevent getting pregnant.
 - You have talked about contraception (birth control) with your doctor. The doctor will give you information how not to get pregnant.
 - Before you start treatment, your doctor may ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with Zematane.
 - You must agree to use at least one very reliable method of contraception (for example an intrauterine device or contraceptive implant) or two effective methods that work in different ways (e.g., a hormonal contraceptive pill and a condom).
 - You must use contraception for a month before taking Zematane, during treatment and for a month afterwards.
 - You must use contraception even if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).
- 2. You are breastfeeding planning to breastfeed.** The medicine is likely to pass into your milk and may harm your baby.
- 3. You have ever had any kind of mental health problems.** This includes depression, aggressive tendencies, or mood changes. It also includes

thoughts about hurting yourself or ending your life. This is because your mood may be affected while taking Zematane.

- 4. You have kidney disease.** Zematane is not recommended for people with moderate kidney disease. If you have kidney disease – check with your doctor that Zematane is suitable for you.
- 5. You have high blood fats;** you may need blood tests more often. Zematane commonly increases blood fats, such as cholesterol or triglycerides. If your blood fats stay high, your doctor may lower your dose, or take you off Zematane.
- 6. You have high blood sugar (diabetes),** your blood sugar levels may need to be checked more often.
- 7. You have been suffering from thyroid disease.** Zematane may lower your thyroid hormone levels.
- 8. You have allergies to:**
- Any other medicines.
 - Any other substances, such as foods, preservatives or dyes.

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

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 taking Zematane.

Do not take other retinoid medicines (e.g., isotretinoin), vitamin A supplements or tetracyclines (a type of antibiotic) while taking Zematane. This increases the risk of side effects.

Some medicines may interfere with Zematane. These include:

- amiodarone (a medicine that helps to regulate heart rate). Amiodarone is not recommended to be taken together with Zematane.
- ketoconazole, fluconazole, miconazole (medicines used to treat infections). Your doctor may decide to reduce your dose of Zematane.
- gemfibrozil (a medicine used to lower cholesterol) or oxandrolone (an anabolic

steroid). Your doctor may decide to reduce your dose of Zematane.

- paclitaxel (used to treat cancer), rosiglitazone or repaglinide (used to treat diabetes).
- simvastatin (a medicine used to lower cholesterol).

These medicines may be affected by Zematane or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

How to take Zematane

How much to take

The dose is either 10 mg or 30 mg once daily. If your body cannot tolerate the recommended 30 mg dose, you may be prescribed the lower 10 mg dose.

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

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

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

How to take it

Zematane should be taken with a main meal. The capsules should be swallowed whole with a glass of water and not chewed.

When to take it

Take Zematane preferably at the same time each day.

How long to take it

A course of treatment usually lasts for 12 to 24 weeks depending how your condition gets better. If your first treatment was successful, your doctor may prescribe another course of treatment if symptoms return.

If you forget to take it

If you miss a dose, take it as soon as you can. However, if it is nearly time for your next dose, skip the missed dose and carry on as before.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking Zematane

Things you must do

- **Mental health problems:**

You may notice some changes in your mood and behaviour and so it is very important that you tell your family and friends that you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor about.

If you develop any mental health problems including depression, aggressive tendencies, mood changes, thoughts about hurting yourself or ending your life, **you must stop taking Zematane immediately and contact your doctor as soon as possible.**

- **Minimise your exposure to sunlight and avoid sun lamps.**

Your skin may become more sensitive to sunlight. Before you go out in the sun, use a sun protection product with a high protection factor. If you get dry skin and lips during treatment, use a moisturising ointment or cream and a lip balm.

- If you develop dry eyes, lubricating eye ointment or tear replacement drops can help. If you wear contact lenses, you may need to wear glasses during alitretinoin treatment. Dry eyes and sight problems normally return to normal once treatment is stopped.

- **If you experience any problems with your eyesight, tell your doctor immediately.** Zematane may need to be stopped and your eyesight monitored.

- **Talk to your doctor if do intensive physical exercise** - alitretinoin can cause muscle and joint pain.
- If you get a persistent headache, nausea or vomiting (feeling or being sick) and blurred vision, these may be signs of a condition called benign intracranial hypertension. **Stop the capsules immediately and contact your doctor as soon as possible.**
- **If you have bloody diarrhoea stop the capsules immediately and contact your doctor as soon as possible.**
- Alitretinoin may increase liver enzyme levels. Your doctor will do blood tests during treatment to check these levels. If they stay high, your doctor may lower your dose or take you off Zematane.
- **If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Zematane.**

If you become pregnant while taking this medicine, stop taking it and tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking 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.

You may require regular tests to check your liver, blood sugar levels and blood cholesterol levels.

Things you must not do

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

Do not donate blood during treatment with Zematane or for at least 1 month after stopping treatment.

Things to be careful of

Be careful driving or operating machinery until you know how Zematane affects you. You may

not see as well at night during your treatment. If this happens to you, you should not drive or operate machinery

Minimise sun exposure and sun lamps and apply sunscreen whilst taking Zematane.

Wearing contact lenses during treatment with Zematane may cause discomfort, wearing glasses maybe needed.

In case of overdose

If you take too much (overdose)

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 taken too much [Trade name].

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 taking Zematane.

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 these symptoms and they worry you:

- Headache
- Raised blood fats such as triglycerides and cholesterol
- Thyroid problems
- Eye problems such as dry and irritated eyes
- Persistent noise in the ears (tinnitus)
- Dizziness
- Flushing, high blood pressure

- Feeling sick (nausea), being sick (vomiting), dry mouth
- Muscle pain, joint pain, lack of energy (fatigue)
- Dryness of the skin, especially of the face, dry and inflamed lips, redness of the skin, itchy skin rash, inflamed skin, hair loss.

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

- Altered mood, anxiety, feelings of emotional discomfort
- Depression
- Existing depression worsening
- Unusual behaviour e.g., becoming aggressive.
- Having thoughts or feelings about harming yourself.
- A loss of contact with reality, such as hearing voices or seeing things that are not there.

If any of the following happen, stop taking Zematane 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; hives; fainting. These are very serious side effects. If you have them, you may have had a serious allergic reaction to Zematane. You may need urgent medical attention or hospitalisation. These side effects are very rare.
- Severe stomach (abdominal) pain, with or without bloody diarrhoea, feeling sick (nausea) and being sick (vomiting). **Stop taking Zematane immediately and contact your doctor. These can be signs of serious gut conditions.**

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

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

After taking Zematane

Storage

Keep your capsules in the original pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

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

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.

Disposal

If your doctor tells you to stop taking 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

Zematane 10 mg: Light brown, oval, soft gelatin capsule.

Zematane 30 mg: Yellow, oval, soft gelatin capsule.

Ingredients

Active ingredient: alitretinoin.

Inactive ingredients: **Capsule content:** Soya-bean oil, refined; Soya-bean oil, partially hydrogenated; Hydrogenated vegetable oil; Glycerol monostearate; Triglycerides, medium chain; All-rac- α -tocopherol; **Capsule shell:** Gelatin; Glycerol; Sorbitol, liquid; Titanium dioxide; Iron oxide, yellow (E172)

Zematane 10 mg also contains: Iron oxide, red (E172); Iron oxide, black (E172).

Sulfur dioxide present as a residue in gelatin.

Sponsor details

Zematane is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

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