

Dermatane™

Isotretinoin 5 mg, 10 mg, 20 mg and 40 mg capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Dermatane. 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 Dermatane against the benefits the medicine is expected to 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 Dermatane is used for

Dermatane contains the active ingredient isotretinoin.

Dermatane is used to treat acne.

Dermatane belongs to a group of medicines called retinoids, which are similar to vitamin A.

The retinoids work by reducing the amount of the oily substance (i.e. sebum) made by glands in your skin, reducing bacteria, reducing inflammation and opening clogged pores.

There are many different types of medicines used to treat acne.

Dermatane is used for more severe cases.

Your doctor may have prescribed Dermatane for another purpose.

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

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

DERMATANE is not addictive.

Before you take it

When you must not take it

Do not take Dermatane if:

- 1. You are pregnant or for at least one month before you intend to become pregnant; If you fall pregnant while taking Dermatane, there is an extremely high risk of having a baby that is severely deformed. You must use effective contraception for one month before, during and one month after treatment with Dermatane.**
- 2. You are breastfeeding; Breastfeeding must stop before Dermatane treatment can begin. Do not breastfeed while taking Dermatane.**
- 3. You have had an allergic reaction to Dermatane, vitamin A, other retinoids or any ingredients of Dermatane listed at the end of this leaflet;**
- 4. You are taking tetracycline antibiotics (such as minocycline or doxycycline);**
- 5. You have severe liver disease;**
- 6. You have very high levels of fat (triglycerides, cholesterol) in your blood;**
- 7. You have an excessive amount of vitamin A in your diet (hypervitaminosis A);**
This is a condition caused by an

excessive amount of vitamin A in the diet

- 8. The packaging is torn or shows signs of tampering; and**
- 9. The expiry date (EXP) printed on the pack has passed.**
If you take this medicine after the expiry has passed, it may not work as well.

If you are not sure if you should start taking Dermatane, contact your doctor.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Do not give Dermatane to children.

There is limited information on the use of Dermatane in children before puberty.

Before you start to take it

You must tell your doctor if:

- 1. You have allergies to other medicines, foods, preservatives or dyes.**
Dermatane contains soya oil, which may contain traces of arachidic acid (a component of peanut oil).
- 2. You have any other health problems or issues including:**
 - diabetes, or a history of diabetes in your family;
 - depression;
 - liver disease;
 - kidney disease;
 - lipid (cholesterol or triglyceride) disorder;
 - hormone disorder; or
 - stomach or bowel disease.

3. You drink large amounts of alcohol.

If you have not told your doctor about any of the above, tell him or her before starting Dermatane.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines interfere with Dermatane. These include:

- tetracycline antibiotics (such as minocycline or doxycycline);
- vitamin A or formulations containing vitamin A (including vitamin supplements);
- other medicines for acne; or
- the “mini-pill”, a progesterone-only oral contraceptive pill.

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

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take it

How much to take

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Take Dermatane exactly as your doctor has prescribed.

Your doctor will tell you how much Dermatane you need to take each day.

This dose will be calculated to suit your individual needs and your body weight. This dose may be adjusted during treatment when the doctor knows how you respond to Dermatane.

How to take it

Dermatane should be swallowed whole with a glass of water or milk.

Do not open capsules or take damaged capsules.

When to take it

Dermatane should be taken once or twice a day and must always be taken with meals.

Female patients should wait until the 2nd or 3rd day of their menstrual period before starting Dermatane.

This helps to ensure that you are not pregnant before you start taking Dermatane.

How long to take it

Continue taking Dermatane for as long as your doctor prescribes.

Acne treatment with Dermatane will usually last 4 to 8 months. In the first few weeks of treatment your acne will probably get a little worse before it gets better. Do not worry about this, it is a sign that Dermatane is working.

At the end of this time your acne should have cleared up significantly. Most patients notice their skin condition continues to improve even after Dermatane treatment is finished.

Please note that Dermatane cannot improve scars or pitting that were present before treatment started, but it will help prevent such skin damage in the future.

If you forget to take it

Do not try to make up for missed doses by taking an extra dose.

This may increase the chance of getting an unwanted side-effect.

If it is almost time for your next dose, skip the dose that you have missed and take the next dose when you are meant to.

If you have missed several doses, please inform your doctor and follow the advice given to you.

If you take too much (overdose)

Immediately telephone your doctor, or Poisons Information Centre (Australia: Ph: 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Dermatane. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of overdose include transient headache, vomiting, facial flushing, reddened, cracked lips, stomach pain, headache, dizziness and unsteady walking.

While you are taking it

Things you must do

If you become pregnant while taking Dermatane, stop taking it and inform your doctor immediately.

Dermatane can cause birth defects (damage to unborn babies). You must use strict birth control for at least 1 month before you begin taking Dermatane, for the whole time you are taking Dermatane and for at least 1 month after you finish taking Dermatane.

There is no known risk to males who wish to father children.

Tell all doctors, dentists and pharmacists who are treating you that you are on Dermatane.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Dermatane.

If you go into hospital, please let the medical staff know you are taking Dermatane.

Tell your doctor if you feel Dermatane is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may ask you to have regular blood tests to monitor your liver function, blood sugar levels and blood cholesterol levels.

If you are intending to do a lot of heavy lifting or exercise, tell your doctor.

Your muscles and joints may be more prone to tenderness or stiffness, if you do a lot of heavy exercise while taking Dermatane.

Things you must not do

Do not stop taking Dermatane or change the dose without first checking with your doctor.

Do not let yourself run out of Dermatane over the weekend or on holidays.

Do not give Dermatane to anyone else even if they have the same condition as you or their symptoms seem similar to yours.

Do not use Dermatane to treat other complaints unless told to by your doctor.

Do not donate blood while taking Dermatane or for at least 1 month after stopping treatment.

Do not take any other medicines without first telling your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Dermatane affects you. Normally Dermatane would not affect your ability to drive a car or operate machinery. However altered night vision and other visual disturbances may occur while taking Dermatane. Make sure you know how you react to Dermatane before you drive a car, operate machinery or do anything else that may be dangerous if your vision is affected.

Wearing contact lenses during treatment with Dermatane may cause discomfort. Dermatane causes dry eyes so an artificial

lubricant might be necessary.

Otherwise, you may temporarily need to wear your lenses for shorter periods or wear glasses instead

Avoid waxing or dermatological abrasions while taking

Dermatane and for six months after Dermatane treatment has stopped.

Your skin may be more sensitive while on Dermatane.

Waxing may cause dermatitis and dermabrasion may cause scarring during and for several months after.

Avoid excessive sun exposure, solariums and always apply sunscreen while taking

Dermatane. Your skin may be more prone to sunburn while on Dermatane.

Avoid using facial peels, electrolysis and some hair

treatments. Your skin and hair will be more delicate during treatment and for a while after Dermatane treatment.

Side effects

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

Dermatane helps most people with acne but it may have unwanted side effects in a few people.

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.

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

- dryness of the lips, mouth, nose, eyes and skin. A moisturiser or petroleum jelly can be used to soften the lining of the nose, lips

and the skin areas not affected by the acne;

- fragile skin;
- change in colour of the skin;
- peeling of skin on palms of hands and soles of feet;
- itchy skin rash;
- an increased susceptibility to sunburn;
- sweating;
- changes to nails;
- eye problems such as dry, sore, swollen or itchy eyes, discharge or trouble seeing at night;
- nosebleeds;
- tenderness, stiffness in bones, joints or muscles;
- headache;
- tiredness;
- hair loss (sometimes occurs and is usually temporary but in rare cases has persisted);
- excessive hairiness; or
- hoarseness.

These side effects are usually mild and dose-related. Most of them disappear completely in a few days to a few weeks after the dose of Dermatane is lowered or stopped.

Tell your doctor immediately if you experience any of the following:

- vomiting;
- nausea;
- persistent headache;
- blurred vision or visual disturbances;
- changes in your hearing or ringing in your ears;
- severe upper stomach pain;
- unexpected muscle pain, tenderness or weakness;
- blood in stools or severe diarrhoea;
- severe bruising;
- sudden red, often itchy spots, similar to the rash of measles starting on the face, hands or feet. The spots may blister or change to flat round, raised, red, pale centred marks. Also you may have fever, sore throat, headache and/or diarrhoea;

- painful red areas that change to large blisters and end with peeling of layers of skin that may occur on the lips, mouth, eyes, nose and genitals. Those affected may have fever and chills, aching muscle and generally feel unwell;
- thinking, seeing or hearing things that are not real; or
- feeling depressed with or without suicidal thoughts.

Symptoms of depression may include:

- feeling sad or have crying spells;
- lose interest in activities you once enjoyed;
- sleep too much or have trouble sleeping;
- have a change in your appetite or body weight;
- have trouble concentrating;
- withdraw from your friends or family;
- feel like you have no energy; or
- have feelings of worthlessness or inappropriate guilt.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

Ask your doctor or pharmacist if you don't understand anything in this list.

After taking it

Storage

Keep your capsules in the blister pack and closed carton until it is time to take them. If you take the capsules out of the blister foil, it will not keep well.

Keep **Dermatane 5 mg, 10 mg and 40 mg** capsules in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.

Keep **Dermatane 20 mg** capsules in a cool dry place where the temperature stays below 30°C. Protect from light and moisture.

Do not store Dermatane or any other medicine in the bathroom or near a sink.

Do not leave Dermatane in the car or on windowsills. Heat and dampness can destroy some medicines.

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

Disposal

Ask your pharmacist what to do with any capsules you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What Dermatane looks like

Dermatane 5 mg* capsules are faint pinkish-cream to cream coloured oval, soft gel capsules, containing a yellow/orange liquid. They are available in blister packs of 15 (sample pack), 30, 60 and 90 capsules.

Dermatane 10 mg* capsules are light violet coloured oval soft gel capsules, containing a yellow/orange liquid. They are available in blister packs of 15 (sample pack) and 60 capsules.

Dermatane 20 mg* capsules are maroon coloured oval soft gel capsules containing a yellow/orange liquid. They are available in blister packs of 60 capsules.

Dermatane 40 mg* capsules are light orange, oval, soft gel capsules

containing a yellow/orange liquid. They are available in blister packs of 15 (sample pack), 30, 60 and 90 capsules.

*Some pack sizes and strengths may not be marketed.

Ingredients

Active ingredient:
Isotretinoin

Inactive ingredients:
All strengths of Dermatane contain the following ingredients: yellow beeswax, butylated hydroxyanisole, disodium edetate, dl-alpha-tocopherol, gelatin, glycerol, sorbitol solution (70 per cent) (non-crystallising), soya oil, partially hydrogenated soya oil, titanium dioxide and purified water.

Additionally the following strengths also contain:

Dermatane 5 mg: hydrogenated vegetable oil.

Dermatane 10 mg: brilliant scarlet 4R, iron oxide black and hydrogenated vegetable oil.

Dermatane 20 mg: brilliant scarlet 4R, indigo carmine and hydrogenated vegetable oil.

Dermatane 40 mg: sunset yellow and hydrogenated soya oil.

Distributor



Eris Pharmaceuticals (Australia) Pty Ltd
6 Eastern Road,
South Melbourne VIC 3205,
Australia
www.eris-pharma.com.au

Toll free telephone (Australia):
1800 233 588

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Dermatane 5 mg capsules blister
pack AUST R 186342

Dermatane 10 mg capsules blister
pack AUST R 144129

Dermatane 20 mg capsules blister
pack AUST R 144130

Dermatane 40 mg capsules blister
pack AUST R 186345

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