

ORATANE*

Isotretinoin

5 mg, 10 mg, 20 mg, 30 mg and 40 mg Capsules

What is in this leaflet

Please read this leaflet carefully before you start taking ORATANE.

This leaflet answers some common questions about ORATANE. 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 ORATANE 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 ORATANE is used for

The active ingredient in ORATANE capsules is isotretinoin, a substance very similar to vitamin A. ORATANE belongs to a group of medicines called retinoids.

ORATANE capsules are used to treat acne. Of the many acne medicines, ORATANE is used for more severe cases.

ORATANE capsules work by cutting down the amount of oily substances (sebum) made by your glands in your skin. ORATANE capsules will also help to reduce the bacteria, inflammation and open clogged pores.

Your doctor may have prescribed ORATANE for another reason.

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

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

ORATANE capsules are not addictive.

Before you take ORATANE

When you must not take it

Do not take ORATANE if you are pregnant or for at least one month before you intend to become pregnant. If you fall pregnant while taking ORATANE capsules, there is an extremely high risk of having a baby that is severely deformed.

Pregnancy testing should be performed before, during (every month is strongly recommended) and for a month after treatment has finished.

You must use effective contraception (birth control) for one month before, during and at least one month after treatment with ORATANE.

It is recommended that two complementary forms of contraception including a barrier method should be used. Progesterone only contraceptive tablets (minipills) alone are not considered an effective method of contraception while you are on ORATANE.

Do not breastfeed while taking ORATANE capsules. Breast-feeding must stop before ORATANE treatment can start.

Do not take ORATANE if you have an allergy to:

- any medicine containing isotretinoin
- other retinoids, including vitamin A
- 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
- hives on the skin, rash, or itching
- swelling of the face, tongue, lips, or other parts of the body

Do not take ORATANE if you are taking tetracycline antibiotics, such as doxycycline, minocycline.

Do not take ORATANE if you have liver disease.

Do not take ORATANE if you have very high levels of fat (triglycerides, cholesterol) in your blood.

Do not take ORATANE if you have very high levels of vitamin A in your body (hypervitaminosis). It is a condition caused by an excessive amount of Vitamin A in the diet.

Do not give ORATANE capsules to children under 12 years.

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, or if the capsules do not look quite right.

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

Before you start to use it

Tell your doctor if you have:

1. **allergies to other substances, such as foods, preservatives or dyes.** Oratane capsules contain soya oil.
2. **ever had any mental illness** (including depression and suicidal behaviour).
3. **liver disease**
4. **kidney disease**
5. **lipid (cholesterol or triglyceride) disorder**
6. **eye disorders**
7. **hearing impairment**
8. **bowel disease**
9. **diabetes** (high blood sugars)

Tell your doctor if you drink large amounts of alcohol.

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

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.

Some medicines may interfere with ORATANE. These include:

- Tetracycline antibiotics
- Vitamin A or formulations containing vitamin A
- Other medicines for acne. **Avoid the use of topical keratolytic or exfoliative anti-acne agents** while you are on ORATANE.
- The mini-pill, a progesterone-only oral contraceptive pill

These medicines may be affected by ORATANE 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.

Talk to your doctor or pharmacist if you are not sure about this list of medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ORATANE.

How to take ORATANE

How much to take

Always take ORATANE exactly as your doctor or pharmacist tells you to. The directions given may differ from information contained in this leaflet.

Your doctor will determine exactly how much ORATANE you need for your condition. This will be matched especially to your needs and your bodyweight and may be adjusted by your doctor when it is known how you respond to ORATANE capsules.

How to take it

Swallow ORATANE capsules whole with a glass of water. Do not open ORATANE capsules or take damaged capsules.

ORATANE must be taken with meals.

When to take it

Take ORATANE at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Female patients should wait until the 2nd or 3rd day of their menstrual period before starting ORATANE. This helps to ensure that you are not pregnant before you start to take ORATANE.

How long to take it

Continue taking ORATANE capsules for as long as your doctor prescribes.

Your treatment with ORATANE will usually last 16 to 24 weeks. Most patients only need one course. Your acne may continue to improve for up to 8 weeks after treatment. Therefore, you will not usually start another course until then.

In the first few weeks your acne may get worse before it gets better. It usually improves as treatment goes on.

Although ORATANE cannot improve scars or pitting that existed before commencement of treatment, it will help prevent further scarring.

If you forget to take it

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

Continue with the next dose when it is due. If you are unsure what to do, ask your doctor or pharmacist. If you have missed several doses, please inform your doctor and follow the advice given to you.

While you are taking ORATANE

Things you must do

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

ORATANE capsules can cause birth defects. This means that **you must use strict birth control for at least 1 month before you start ORATANE, the whole time you are using ORATANE capsules and for at least 1 month after you finish taking ORATANE capsules.**

No specific contraceptive precautions are necessary for men. Although isotretinoin and its metabolites are present in very low levels in your semen, these levels are considered too low to harm the unborn baby of your female partner. However, you must never share your medication with anyone.

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

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. Your doctor may decide to monitor your bone growth and bone structure, particularly if you are a child or young person.

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

If you have not taken your medicine exactly as prescribed, you must inform your doctor. Your doctor may think ORATANE was not effective and change your treatment unnecessarily.

If you are intending to do a lot of heavy lifting or intensive exercise, tell your doctor. Your muscles and joints may become stiff or tender while taking ORATANE.

Things you must not do

Do not give ORATANE capsules to anyone else, even if their symptoms seem similar to yours.

Do not donate blood while taking ORATANE or for at least four weeks after stopping treatment because an unborn baby could be harmed if a pregnant patient receives your blood.

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

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

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

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 ORATANE affects you.

Normally ORATANE capsules would not affect your ability to drive a car or operate machinery. However altered night vision and other visual disturbances may occur while taking ORATANE capsules. Make sure you know how you react to ORATANE capsules before you drive a car, operate machinery or do anything else that might be dangerous if your vision is altered.

ORATANE may cause dry eyes, intolerance to contact lenses and visual difficulties including decreased night vision. Tell your doctor if you have any of these symptoms. Your doctor may ask you to use lubricating eye ointment or artificial tears. If you use contact lenses and you have developed intolerance to contact lenses, you may be advised to wear glasses during the treatment. Your doctor may refer you to a specialist for advice if you develop visual difficulties and you may be asked to stop taking ORATANE.

Avoid waxing, dermatological abrasions, facial peels, electrolysis while taking ORATANE and for six months after ORATANE treatment has

stopped. Your skin may be more sensitive while on ORATANE.

Avoid using hair colouring, perming products. Your skin and hair will be more delicate while taking ORATANE.

Avoid excessive sun exposure, and always apply sunscreen while taking ORATANE. Your skin may be more prone to sunburn.

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 ORATANE. 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 or cracked lips, stomach pain, headache, dizziness and unsteady walking.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking ORATANE. In addition to the beneficial effects of ORATANE for acne, it is possible that unwanted effects will occur during treatment, even when it is used as directed.

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.

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

- Peeling of skin on palms of hands and soles of feet
- Skin redness, rash, itching, inflammation
- Dryness of the vulva or vagina
- Tenderness, stiffness in bones, joints or muscles
- Headache
- Nosebleeds
- Increased sensitivity to sunlight
- Temporary hair loss (in some rare cases hair loss has persisted)
- Problems getting or maintaining an erection
- Lower libido
- Persistent pain in your lower back or buttocks during treatment with ORATANE. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with ORATANE and refer you to a specialist for treatment of inflammatory back pain. Further evaluation may be needed including use of various imaging techniques such as MRI.
- Pain and/or difficulty passing urine. This may be a sign of inflammation of the urethra also known as urethritis.

These side effects are usually mild and dose related. After the dose of ORATANE capsules is reduced or stopped most of these side effects should disappear within a few days or weeks.

Stop taking ORATANE capsules and contact your doctor immediately if you experience any of the following:

- Bloody diarrhoea, blood in urine
- Nausea, vomiting, stomach pain or fever
- Persistent headache, severe headache, or seizure
- Blurred vision or visual disturbances
- changes in your hearing or ringing in your ears.
- Unexpected muscle pain or weakness
- 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. You may also have a 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 lips, mouth, eyes, nose and genitals. Those affected may have fever and chills, aching muscles and generally feel unwell.

- Feeling depressed with or without suicidal thoughts
- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry or aggressive than usual (e.g., temper outbursts, thoughts of violence)
- Change in appetite or body weight
- Have trouble concentrating
- Withdraw from family or friends
- Feel like you have no energy
- Have feelings of worthlessness or inappropriate guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts).

These may be serious side effects and may require urgent medical attention.

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

You should tell your doctor about unwanted effects that occur during treatment. In some cases you doctor may want to reduce your dose or stop treatment.

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

After taking ORATANE

Storage

Keep your capsules in the blister pack until it is time to take them. If you take the capsules out of the packaging they will not keep as well.

Keep ORATANE 5 mg, ORATANE 10 mg, ORATANE 30 mg, ORATANE 40 mg capsules in a cool dry place where the temperature stays below 25°C. Protect from light.

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

Do not store ORATANE 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 ORATANE capsules 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

Return any unused medicine to your pharmacist. 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.

Product description

What it looks like

ORATANE 5 mg capsules are soft, oval, opaque white in colour containing a yellow/orange liquid.

ORATANE 10 mg capsules are soft, oval, opaque light violet in colour containing a yellow/orange liquid.

ORATANE 20 mg capsules are soft, oval, opaque maroon-red in colour containing a yellow/orange liquid.

Oratane 30 mg capsules are soft, oval opaque pink in colour, containing a yellow/orange liquid.

ORATANE 40 mg capsules are soft, oval, opaque light orange in colour containing a yellow/orange liquid.

Ingredients

Active ingredient(s):

Isotretinoin

Inactive ingredients:

Soya oil, tocopherol, disodium edetate, butylated hydroxyanisole, yellow beeswax, hydrogenated soya oil.

The capsule shells contain:

Gelatin, glycerol, sorbitol solution 70% (non-crystallising), titanium dioxide and water (purified).

10 mg capsules only: Iron oxide black (CI 77499) and Ponceau Red (CI 16255).

20 mg capsules only: Indigo carmine (CI 73015) and Ponceau Red (CI 16255).

30 mg capsules only: Iron oxide red

40 mg capsules only: Sunset yellow (CI 15985).

Sulfur dioxide present as a residue in gelatin.

Sponsor details

ORATANE 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

10 December 2024

(based on data sheet dated 10 December 2024)

*Oratane is a registered trademark in New Zealand and other countries