

Oratane 5mg, 10 mg and 20 mg Capsules

(Isotretinoin)

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What ORATANE capsules is used for

The active ingredient in **ORATANE capsules** is Oratane, 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.

Your doctor may have prescribed ORATANE for another purpose.

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

ORATANE capsules are not addictive.

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

Before you use ORATANE capsules

- *When you must not use it*

Do not take ORATANE capsules if:

1. **Do not use if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information. If you fall pregnant while taking ORATANE capsules there is an extremely high risk of having a baby that is severely deformed. This means that you must use effective contraception for one month before, during and at least one month after treatment with ORATANE.**
2. **You are breast-feeding.** Breastfeeding must stop before ORATANE treatment can start. Do not breast-feed while taking ORATANE capsules.
3. **You have had an allergic reaction to ORATANE capsules, Vitamin A, other retinoids or any ingredients listed at the end of this leaflet.**
4. **You are taking tetracycline antibiotics.** These include Doxine®, DoxyTM Achromycin®, and Minomycin®.
5. **You have kidney or 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).**
8. **The packaging is torn or shows signs of tampering, or if the capsules do not look quite right.**
9. **The expiry date (EXP) date 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 ORATANE capsules, consult your doctor.

Do not give ORATANE capsules to children. There is very little information available on the effects of ORATANE in children.

- *Before you start use it*

WARNING

CAN SERIOUSLY HARM AN UNBORN BABY

Women must use effective contraception

Do not use if you are pregnant or you think you may be pregnant

When you must not use it:

- If you are pregnant or breast-feeding.
- If there is any chance you could become pregnant

Women must use effective contraception before, during and after taking Oratane:

- 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 (for example a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.
- You must use contraception for a month before taking Oratane 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).

Women must agree to pregnancy testing before, during and after taking Oratane

- You must agree to regular follow-up visits, ideally every month
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, 1 month after stopping Oratane (unless you doctor decides this is not necessary in your case).
- You must agree to extra pregnancy tests if your doctor asks you
- You must not get pregnant during treatment or for a month afterwards because some medicine may still be left in your body

If you get pregnant while taking Oratane, stop taking the medicine straight away, and contact your doctor.

Also, if you become pregnant within one month after you stop taking Oratane, you should contact your doctor.

Advise for men

The levels of oral retinoid in the semen taking Oratane are too low to harm their partners' unborn baby. However, you must never share your medication with anyone, especially females.

Additional precautions

You should never give this medicinal product to another person. Please take any unused capsules to you pharmacist at the end of treatment.

You should not donate blood during treatment with this medicine and for 1 month after stopping Oratane because an unborn baby could be harmed if a pregnant patient receives your blood.

You must tell your doctor if:

1. **You have allergies to other substances, such as foods, preservatives or dyes.**
2. **You have any other health problems or issues including:**
 - Diabetes, or family members with diabetes.
 - You drink large amounts of alcohol.

Talk to your doctor before taking ORATANE capsules if you have ever had any kind of mental problem. This includes depression, aggressive tendencies or mood changes. It also includes suicidal thoughts.

Mental health problems

Your mood may be affected while taking **ORATANE capsules**. You may not notice some changes in your mood and behavior and so it is very important that you tell your friends and family 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 have not told your doctor about any of the above, tell him or her before starting ORATANE capsules.

- *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 ORATANE capsules. These include:

- Tetracycline antibiotics, including Doxine®, DoxyTM Achromycin®, and Minomycin®.
 - Vitamin A or formulations containing vitamin A.
 - Other medicines for acne.
 - The mini-pill, a progesterone-only oral contraceptive pill.
- These medicines may be affected by ORATANE capsules, 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.

How to use ORATANE capsules

- *How much to use*

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.

- *When to use it*

ORATANE capsules are taken once or twice a day and must be taken with meals.
ORATANE capsules should be swallowed whole with a glass of water or milk.

Do not open ORATANE capsules or take damaged ORATANE capsules.

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

This helps to ensure that you are not pregnant before you start to take ORATANE therapy

- *How long to use it*

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

Your treatment with ORATANE will usually last 16 weeks. Sometimes a second course of treatment may be necessary. In the first few weeks your acne will probably get worse before it gets better. Do not worry as this is a sign the ORATANE capsules are working.

After this treatment period your skin should have cleared up significantly. Skin condition continues to improve even after ORATANE treatment has finished.

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

- *If you forget to use it*

If you forget to take ORATANE, you should not make up for missing the dose by doubling the next dose.

You should simply continue with the next dose when it is due.

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

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of 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 require urgent medical attention.

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

While you are using it ORATANE capsules

- *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.

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 ORATANE capsules.

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

But also tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

If you are intending to do a lot of heavy lifting or exercise, tell your doctor.
ORATANE capsules can make your muscles and joints prone to stiffness or tenderness.

Be sure to keep all of your appointments with your doctor so he or she can monitor your progress.

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

- Things you must not do
Do not stop taking ORATANE capsules 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 give ORATANE capsules to anyone else, even if their symptoms seem similar to yours.

Do not donate blood while taking ORATANE capsules or for at least four weeks 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 ORATANE capsules affect 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.

Wearing contact lenses during treatment with ORATANE capsules may cause discomfit. ORATANE capsules cause dry eyes so an artificial lubricant might be necessary. Otherwise you might need to compensate by wearing your glasses.

Avoid waxing or dermatological abrasions while taking ORATANE capsules and for six months after ORATANE treatment has stopped.
Your skin may be more sensitive while on ORATANE capsules.

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

Avoid using facial peels, electrolysis and some hair treatments. Your skin and hair will be more delicate while taking ORATANE capsules.

Side effects
Tell your doctor or pharmacist as soon as possible if you do not feel well while taking ORATANE capsules.

In addition to the beneficial effects of ORATANE 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. Soften these areas not affected by acne, with moisturiser or petroleum jelly to avoid dryness
- Nosebleeds
- Tenderness, stiffness in bones, joints or muscles
- Peeling of skin on palms of hands and soles of feet
- Headache
- Tiredness
- Eye problems
- Increased chance of sunburn
- Temporary hair loss (in some rare cases hair loss has persisted)

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.

However, Oratane has been associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. Patients experiencing severe (haemorrhagic [bloody]) diarrhoea should discontinue Oratane immediately.

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

- Bloody diarrhoea
- Vomiting
- Nausea
- Persistent headache
- Blurred vision or visual disturbances
- 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 (eg: 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. 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 unknown side effects.

You should tell your doctor about unwanted effects that occur during treatment. In some cases your 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.
If you are concerned about these or any other unexpected effects, please talk to your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ORATANE Capsule
- 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 capsules in a cool dry place where the temperature stays below 30°C. Protect from light.

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

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

Keep ORATANE capsules 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
Tell your doctor if you stop taking the capsules or the capsules have passed their expiry date; ask your pharmacist what to do with any capsules that are left over.

Product Description
- What it looks like
ORATANE 5 mg capsules are faint pinkish-cream to cream coloured, oval, soft-gelatin capsules containing a yellow/orange, opaque, viscous 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.

- Ingredients
- Active ingredient
Oratane

- Inactive ingredient
Soya oil, DL- α -tocopherol, disodium edetate, butylated hydroxyanisole, partly hydrogenated soya oil, 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).

- MAL number:
Oratane 5mg capsules:
MAL15085073ACZ

Oratane 10mg capsules:
MAL20040050ACRZ

Oratane 20mg capsules:
MAL20033515ARZ

Manufacturer
Swisscap AG
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Switzerland

Product Registration Holder
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Date of revision
March 2023

Serial Number
NPRA(R2/1)190524/154

306772