



Osimertinib (Tagrisso®)

Pronounce: oh-si-mer-ti-nib

Classification: tyrosine kinase inhibitor

About Osimertinib (Tagrisso®)

A kinase is an enzyme that promotes cell growth. There are many types of kinases that control different phases of cell growth. By blocking a certain enzyme from working, this medication can slow the growth of cancer cells. Osimertinib works by targeting and blocking epidermal growth factor receptor (EGFR) tyrosine kinase.

In some cancers, this receptor is overactive, causing cells to grow too fast. By inhibiting EGFR, osimertinib stops tumor growth. Your oncology team will test your tumor for this abnormality, which must be present in order to receive the medication.

How to Take Osimertinib

Osimertinib is taken by mouth, in tablet form. If you miss a dose, do not take two doses to make up for a missed dose. If you vomit after taking your dose, do not take another dose. Take the next dose at its normally scheduled time. Consult with your pharmacist or provider if you are having trouble swallowing the medication.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

If you have trouble swallowing pills, the tablet can be placed in a container with 60ml (2 ounces) of non-carbonated water. Do not crush the tablet or heat the liquid. Stir until the tablet is in small pieces (it will not dissolve completely). You can drink the water or administer the medication through a naso-gastric tube. Add an additional 120ml to 240ml (4 to 8 ounces) of water to the container and either drink or administer the fluid into the naso-gastric tube to ensure the entire dose is administered.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, verapamil, ketoconazole, itraconazole, rifampin, phenytoin, St. John's wort, modafinil, telithromycin, and ritonavir. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your pharmaceutical insurance coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects

There are a number of things you can do to manage the side effects of osimertinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Low White Blood Cell Count (Leukopenia, Lymphopenia, Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your [WBC count can drop](#), putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips for preventing infection:

- [Washing hands](#), both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent [mouth care](#).
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

Diarrhea

Your oncology care team can recommend medications to relieve [diarrhea](#). Also, try eating [low-fiber](#), bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the [count is low](#) you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in

your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Nail and Skin Changes

This medication has some unique nail and skin side effects that you may develop. Patients may develop a rash. While this rash may look like acne, it is not, and should **not** be treated with acne medications. The rash may appear red, swollen, crusty, dry and feel sore. You may also develop very dry skin, which may crack, be itchy or become flaky or scaly. The rash typically starts in the first week of treatment, but can occur at any time during treatment. Tips for managing your skin include:

- Use a thick, alcohol-free emollient lotion or cream on your skin at least twice a day, including right after bathing.
- Avoid sun exposure, as it can worsen the rash or cause a severe burn. Use a sunscreen with an SPF of 30 or higher and wear a hat and sunglasses to protect your head and face from the sun.
- Bathe/shower in cool or lukewarm (not hot) water and pat your skin dry.
- Use soaps, lotions and laundry detergents without alcohol, perfumes, or dyes.
- Wear gloves to wash dishes or do housework or gardening.
- Drink plenty of water and try not to scratch or rub your skin.
- Notify your healthcare team if you develop a rash, as they can provide suggestions to manage the rash and/or prescribe a topical medication to apply to the rash or an oral medication.
- If you develop peeling or blistering of the skin, notify your healthcare team right away.

While receiving this medication, you may develop an inflammation of the skin around the nail bed/cuticle areas of toes or fingers, which is called paronychia. It can appear red, swollen or pus filled. Nails may develop "ridges" in them or fall off. You may also develop cuts or cracks that look like small paper cuts in the skin on your toes, fingers or knuckles. These side effects may appear several months after starting treatment, but can last for many months after treatment stops.

- Follow the same recommendations for your skin (above).
- Don't bite your nails or cuticles or cut the cuticles.
- Keep your fingernails and toenails clean and dry.
- You may use nail polish, but do not wear fake nails.
- Notify your doctor or nurse if any nails fall off or you develop any of these side effects or other skin abnormalities.

This medication can also cause inflammation of the blood vessels in your skin which causes red or purple spots on your skin that do not go away when you press on them. They can appear on your lower arms, lower legs, trunk, or buttocks. They look like bruises and if they do not go away after 24 hours you should contact your provider.

Mouth Ulcers (Mucositis)

Certain cancer treatments can cause [sores or soreness in your mouth](#) and/or throat. This can make it hard to

swallow, eat, and drink. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing [regular mouth care](#) can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight-ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the [red cell count is low](#), you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing, or pain in your chest. If the count gets too low, you may receive a blood transfusion.

High Blood Sugar (Hyperglycemia)

This medication can cause high blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

Electrolyte Abnormalities

This medication can affect the normal levels of electrolytes (magnesium, sodium etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

Fatigue

[Fatigue](#) is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Important but Less Common Side Effects

- **Eye Concerns:** While receiving this medication, some patients may develop irritation or damage to the cornea (clear part covers the eyeball), changes in your eyesight, watery or dry eyes. Notify your healthcare team if you develop any eye pain, swelling or redness of the eye, any vision changes, including blurriness, seeing floaters, and sensitivity to light.
- **Lung Changes:** Osimertinib can cause changes to your lungs including interstitial lung disease and pneumonitis. Contact your provider if you are experiencing any new or worsening lung symptoms, including shortness of breath, difficulty breathing, new cough, or fever.
- **Heart Problems:** This medication can cause the development or worsening of, congestive heart failure, decreased left ventricular ejection fraction, and an abnormal heart rhythm called QT prolongation. Your heart function will be tested prior to you starting the medication with an electrocardiogram. Notify your healthcare provider if you develop swelling of the feet or ankles,

shortness of breath, feel abnormal heartbeats, or if you feel dizzy or faint.

- **Aplastic Anemia:** This is a condition in which your bone marrow can not make enough new blood cells. Your providers will monitor your blood counts. If you have a fever that does not go away, are bruising more easily, are paler than normal, and are extra tired or weak, you should talk to your provider.

Sexual and Reproductive Concerns

This medication may affect your reproductive system, resulting in the menstrual cycle or sperm production becoming irregular or stopping permanently. Women may experience menopausal effects including hot flashes and [vaginal dryness](#). In addition, the desire for sex may decrease during treatment. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 6 weeks after treatment for women and 4 months after treatment for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you can still be fertile and conceive. You should not breastfeed while taking this medication and for the two weeks after your last dose.

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