

## Osimertinib (Tagrisso)

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### About This Medicine

OSIMERTINIB (OH sim ER ti nib) treats lung cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Diarrhea (loose bowel movements)
- Tiredness
- Muscle and bone pain
- Cough
- COVID-19
- Inflammation (swelling) and/or scarring of the lungs. You may have a cough and/or trouble breathing.
- Rash and dry skin
- Changes in your kidney function
- Changes in your nail color. You may have nail loss and/or brittle nail. Your nails or the tissue around your nails may become inflamed or infected.

**Note:** Each of the side effects above was reported in greater than 20% of people treated with osimertinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- Changes in your heart function such as congestive heart failure - your heart is not pumping blood as well as it should be, and fluid can build up in your body. This can be life-threatening.



- Abnormal electrocardiogram (EKG/ECG)
- Severe inflammation and/or scarring of the lungs which may be life-threatening
- Blurred vision or other changes in eyesight. You may have watery eyes or become sensitive to light. Your eyes and eye lids may become red and painful.
- Severe allergic skin reaction. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Inflammation of the blood vessels in your skin which can cause red or purple spots on your skin
- Aplastic anemia- your bone marrow is unable to produce new blood cells, which can be life-threatening. This can increase your risk of infection, bleeding and make you tired and weak.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

## How to Take Your Medicine

- Swallow the medicine whole with or without food.
- If you have trouble swallowing, disperse the tablet in 2 ounces of non-carbonated water only. Stir the mixture until the tablet is dispersed into small pieces (the tablet will not completely dissolve). Swallow immediately. Rinse the glass with 4 to 8 ounces of water and drink immediately. Do not crush or heat tablet during preparation.
- **Missed dose:** If you miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- To decrease the risk of infection, wash your hands regularly.



- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Keeping your nails moisturized may help with brittleness.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

## Food and Medicine Interactions

- There are no known interactions of osimertinib with food.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with osimertinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness and weakness that interferes with your daily activities



- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Blurred vision or other changes in eyesight
- Teary eyes
- Red or painful eye
- Sensitivity to light
- Wheezing and/or trouble breathing
- Pain in your chest
- Dry cough and/or cough that is bothersome
- New loss of taste or smell
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Pain in your mouth or throat that makes it hard to eat or drink
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Swelling of the legs, feet, or ankles
- Weight gain of 5 pounds in one week (fluid retention)
- Signs of inflammation/infection (redness, swelling, pain) of your nails or the tissue around your nails
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Dry skin that is bothersome
- Red or purple spots on your skin (forearms, lower legs, or buttocks) or hives on the main part of your body (trunk) that do not go away within 24 hours and look bruised
- Decreased or very dark urine
- Pain that does not go away, or is not relieved by prescribed medicines

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 6 weeks after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 4 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 2 weeks after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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