

## Osimertinib (Tagrisso)

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### About This Drug

Osimertinib is used to treat cancer. It is given orally (by mouth).

### 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
- Rash and dry skin
- Changes in your nail color. You may have nail loss and/or brittle nail.

**Note:** Each of the side effects above was reported in greater than 20% of patients treated with osimertinib. Not all possible side effects are included above.

### 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)
- Inflammation (swelling) and/or scarring of the lungs, which can be life-threatening. You may have a cough and/or trouble breathing.
- 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.
- Vasculitis - inflammation of the blood vessels that may cause them to become thick, narrow, scarred, or weak.

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

## How to Take Your Medication

- Swallow the medicine whole with or without food.
- If you have difficulty 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 vomit or miss a dose, take your next dose at the regular time, and contact your physician. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **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 medication 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 nurse or your doctor 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. 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 doctor or nurse 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 nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 nurse or doctor 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 doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor 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 doctor or nurse if you are experiencing pain.

## Food and Drug Interactions

- There are no known interactions of osimertinib with food.
- Check with your doctor or pharmacist 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 drug interactions with osimertinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This drug may interact with St. John's Wort and may lower the levels of the drug in your body, which can make it less effective.

## When to Call the Doctor

Call your doctor or nurse 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
- 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) 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
- Pain that does not go away, or is not relieved by prescribed medicines
- If you think you may be pregnant or may have impregnated your partner

## Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 6 weeks after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 months after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 2 weeks after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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