Osimertinib (Tagrisso®)

About This Drug

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

Possible Side Effects

- Tiredness
- Decreased appetite (decreased hunger)
- Loose bowel movements (diarrhea)
- Rash and dry skin
- Changes in your nail color. You may have nail loss and/or brittle nail.
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Electrolyte changes
- Changes in your liver function
- Blood sugar levels may change. If you have diabetes, changes may need to be made to your diabetes medication.
- Bone marrow depression. 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 (fatigue), and raise your risk of bleeding.

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

Warnings and Precautions

- Changes in the tissue of the heart. Some changes may happen that can cause your heart to have less ability to pump blood.
- Abnormal heart beat/EKG
- Inflammation (swelling) of the lungs. You may have a dry cough or trouble breathing.
- Blurred vision or other changes in eyesight. You may have watery eyes. Your eyes and eye lids may become red and painful.
**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. Do not chew, break, cut or crush it.
- 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. Discuss with your nurse or your doctor how to dispose of unused medicine.

**Treating Side Effects**

- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack water in the body from losing too much fluid).
- If you have diarrhea, 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.
- To help with decreased appetite, eat small, frequent meals.
- Eat high caloric food such as pudding, ice cream, yogurt and milkshakes.
- 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 day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
• To decrease 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 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.

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.
• Avoid the use of St. John’s Wort while taking osimertinib as this 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 100.5 F (38 C) or higher
• Chills
• Fatigue that interferes with your daily activities
• Feeling dizzy or lightheaded
• Easy bleeding or bruising
• Blurred vision or other changes in eyesight
• Red or painful eye
• Trouble breathing
• Pain in your chest
• Dry cough
• Feeling that your heart is beating in a fast or not normal way (palpitations)
• Lasting loss of appetite or rapid weight loss of five pounds in a week
• Pain in your mouth or throat that makes it hard to eat or drink
• Loose bowel movements (diarrhea) 4 times a day or loose bowel movements with lack of strength or a feeling of being dizzy
• A new rash or a rash that is not relieved by prescribed medicines
• Abnormal blood sugar
• Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
• Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
• Swelling of legs, ankles, or feet
• Weight gain of 5 pounds in one week (fluid retention)
• 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 treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 months after your cancer 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 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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