

PATIENT INFORMATION

TAGRISSO® (tuh-GRISS-oh) (osimertinib) tablets

What is the most important information I should know about TAGRISSO?

TAGRISSO may cause serious side effects, including:

- **Lung problems.** TAGRISSO may cause severe lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening lung symptoms, including trouble breathing, shortness of breath, cough, or fever.
 - **Heart problems, including heart failure.** TAGRISSO may cause heart problems that may lead to death. Your healthcare provider should check your heart function before you start taking TAGRISSO and during treatment as needed. Tell your healthcare provider right away if you have any of the following signs and symptoms of a heart problem: feeling like your heart is pounding or racing, shortness of breath, swelling of your ankles and feet, dizziness, feeling lightheaded, or feeling faint.
 - **Eye problems.** TAGRISSO may cause eye problems. Tell your healthcare provider right away if you have symptoms of eye problems which may include watery eyes, sensitivity to light, eye pain, eye redness, or vision changes. Your healthcare provider may send you to see an eye specialist (ophthalmologist) if you get eye problems with TAGRISSO.
 - **Skin problems.** TAGRISSO may cause skin problems. Tell your healthcare provider right away if you develop skin reactions that look like rings (target lesions), severe blistering or peeling of the skin.
 - **Inflammation of the blood vessels in your skin.** TAGRISSO may cause blood vessel problems in your skin. Tell your healthcare provider right away if you develop purple spots or redness of the skin that does not fade in color when pressed (non-blanching) on your lower arms, lower legs, or buttocks or large hives on the main part of your body (trunk) that do not go away within 24 hours and look bruised.
 - **Blood and bone marrow problems.** TAGRISSO may cause a condition where your bone marrow cannot make enough new blood cells (aplastic anemia), and which may lead to death. Your healthcare provider will monitor your blood cell counts before you start and during treatment with TAGRISSO. **Tell your healthcare provider right away** if you develop any signs or symptoms of blood and bone marrow problems, including:

○ a new fever or fever that does not go away (temperature 100.4°F or higher)	○ easy bruising or bleeding that will not stop	○ infection
	○ unusually pale skin	○ tiredness
		○ weakness
- See “What are the possible side effects of TAGRISSO?” for more information about side effects.

What is TAGRISSO?

TAGRISSO is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that has certain abnormal epidermal growth factor receptor (EGFR) gene(s):

- to help prevent your lung cancer from coming back after your tumor(s) has been removed by surgery, **or**
- when your lung cancer has spread to nearby tissues (locally advanced) that is unable to be removed (unresectable) by surgery and has responded or stabilized following chemotherapy and radiation treatment, **or**
- as your first treatment when your lung cancer has spread to other parts of the body (metastatic), **or**
- in combination with pemetrexed and platinum-based chemotherapy, as your first treatment when your lung cancer has spread to nearby tissues (locally advanced) or to other parts of the body (metastatic).
- when your lung cancer has spread to other parts of the body (metastatic), and you have had previous treatment with an EGFR tyrosine kinase inhibitor (TKI) medicine that did not work or is no longer working.
- Your healthcare provider will perform a test to make sure that TAGRISSO is right for you.
- It is not known if TAGRISSO is safe and effective in children.

Before taking TAGRISSO, tell your healthcare provider about all of your medical conditions, including if you:

- have lung or breathing problems other than your lung cancer.
- have heart problems, including a condition called long QTc syndrome.
- have problems with your electrolytes, such as sodium, potassium, calcium, or magnesium.
- have a history of eye problems.
- are pregnant or plan to become pregnant. TAGRISSO can harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with TAGRISSO or think you may be pregnant.
 - **Females** who are able to become pregnant should have a pregnancy test before starting treatment with TAGRISSO. You should use effective birth control (contraception) during treatment with TAGRISSO and for 6 weeks after the last dose of TAGRISSO.
 - **Males** who have female partners that are able to become pregnant should use effective birth control during treatment with TAGRISSO and for 4 months after the last dose of TAGRISSO.
- are breastfeeding or plan to breastfeed. It is not known if TAGRISSO passes into your breast milk. Do not breastfeed during treatment with TAGRISSO and for 2 weeks after your last dose of TAGRISSO. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. Especially tell your healthcare provider if you take a heart or blood pressure medicine.

How should I take TAGRISSO?

- Take TAGRISSO exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with TAGRISSO if you have side effects.
- Take TAGRISSO 1 time each day.
- You can take TAGRISSO with or without food.
- If you miss a dose of TAGRISSO, do not make up for the missed dose. Take your next dose at your regular time.
- **If you cannot swallow TAGRISSO tablets whole:**
 - Place your dose of TAGRISSO in a container that contains 60 mL (2 ounces) of water. Do not use carbonated water or any other liquids.
 - Stir the TAGRISSO tablet and water until the TAGRISSO tablet is in small pieces (the tablet will not completely dissolve). Do not crush, heat, or use ultrasound to prepare the mixture.
 - Drink the TAGRISSO and water mixture right away.
 - Add 120 mL to 240 mL (4 to 8 ounces) of water into the container and drink to make sure that you take your full dose of TAGRISSO.
- **If you have a nasogastric (NG) tube:**
 - Follow the same instructions for mixing TAGRISSO tablets in a container that contains 15 mL of water. **Do not** use carbonated water or any other liquids.
 - Stir the TAGRISSO tablets and water until the TAGRISSO tablets are in small pieces (the tablets will not completely dissolve). Do not crush, heat, or use ultrasound to prepare the mixture.
 - Add another 15 mL of water into the container to make sure no pieces of TAGRISSO tablet remain.
 - Give the TAGRISSO tablet and water mixture using the NG tube manufacturer instructions within 30 minutes.
 - Add another 30 mL of water into the syringe and give the water and any remaining TAGRISSO through the NG tube to make sure that all of the medicine is given. Repeat this step until no pieces remain in the syringe. This will help to ensure that the full prescribed dose of the TAGRISSO is given.

What are the possible side effects of TAGRISSO?

TAGRISSO may cause serious side effects:

- See “What is the most important information I should know about TAGRISSO?”

The most common side effects of TAGRISSO when given alone include:

- low white blood cell counts
- low platelet counts
- low red blood cell counts (anemia)
- diarrhea
- rash
- muscle, bone, or joint pain
- changes in your nails, including: redness, tenderness, pain, inflammation, brittleness, separation from the nailbed, and shedding of nail
- dry skin
- mouth sores
- tiredness

The most common side effects of TAGRISSO when given alone after treatment with platinum-based chemotherapy and radiation treatment include:

- low white blood cell counts
- lung problems
- low platelet counts
- rash
- diarrhea
- changes in your nails, including: redness, tenderness, pain, inflammation, brittleness, separation from the nailbed, and shedding of nail
- cough
- COVID-19

The most common side effects of TAGRISSO in combination with pemetrexed and platinum-based chemotherapy include:

- low white blood cell counts
- low platelet counts
- rash
- diarrhea
- mouth sores
- changes in your nails, including: redness, tenderness, pain, inflammation, brittleness, separation from the nailbed, and shedding of nail
- dry skin
- increase of a substance in the blood called creatinine

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of TAGRISSO. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TAGRISSO?

- Store TAGRISSO at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or that you no longer need.
- **Keep TAGRISSO and all medicines out of the reach of children.**

General information about the safe and effective use of TAGRISSO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TAGRISSO for a condition for which it was not prescribed. Do not give TAGRISSO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TAGRISSO that is written for health professionals.

What are the ingredients in TAGRISSO?

- **Active ingredient:** osimertinib

Inactive ingredients: mannitol, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, and sodium stearyl fumarate. Tablet coating contains: polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, ferric oxide yellow, ferric oxide red and ferric oxide black.

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For more information, go to www.Tagrisso.com or call 1-800-236-9933.