

**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 lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your doctor 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 doctor should check your heart function before you start taking TAGRISSO and during treatment as needed. Tell your doctor 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, feeling lightheaded.
- **eye problems.** TAGRISSO may cause eye problems. Tell your doctor 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 doctor may send you to see an eye specialist (ophthalmologist) if you get eye problems with TAGRISSO.

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 non-small cell lung cancer (NSCLC). TAGRISSO may be used when your non-small cell lung cancer has spread to other parts of the body and:

- has a certain type of abnormal epidermal growth factor receptor (EGFR) gene, called T790M, **and**
- you have had previous treatment with an EGFR tyrosine kinase inhibitor medicine and it has stopped working.

Your doctor 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 doctor about all of your medical conditions, including if you:**

- have lung or breathing problems.
- 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 doctor right away if you become pregnant during treatment with TAGRISSO or think you may be pregnant.
  - **Females** who are able to become pregnant should use effective birth control during treatment with TAGRISSO and for 6 weeks after the final 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 final 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 final dose of TAGRISSO. Talk to your doctor about the best way to feed your baby during this time.

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

**How should I take TAGRISSO?**

- Take TAGRISSO exactly as your doctor tells you to take it.
- Your doctor 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.

**What are the possible side effects of TAGRISSO?****TAGRISSO may cause serious side effects, including:**

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

**The most common side effects of TAGRISSO are:**

- diarrhea
- rash
- dry skin
- changes in your nails, including: redness, tenderness, pain, inflammation, brittleness, separation from nailbed, and shedding of nails
- tiredness

Tell your doctor 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 doctor 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 doctor or pharmacist for information about TAGRISSO that is written for a healthcare professional.

**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.

For more information, go to [www.Tagrisso.com](http://www.Tagrisso.com) or call 1-800-236-9933.

Distributed by: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

©AstraZeneca 2017