

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

TAGRISSO®

Osimertinib tablets

Read this carefully before you start taking **TAGRISSO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TAGRISSO**.

Serious Warnings and Precautions

TAGRISSO should only be prescribed by a doctor with experience in the use of anti-cancer drugs.

These are rare but serious side effects that have been seen in patients taking TAGRISSO:

- **Serious Lung Problems (interstitial lung disease (including pneumonitis)):** This can cause inflamed or scarred lungs and death in some cases.
- **Serious Electrical Problems with the Heart: Abnormal electrical signal of the heart (QT interval prolongation).**
- **Heart Failure and an Enlarged Heart: When your heart is weak and can't pump well enough to get blood to the body. It may lead to death.**

What is TAGRISSO used for?

TAGRISSO is used in adults to treat a type of cancer called 'non-small cell lung cancer'. It is used when your cancer is locally advanced or metastatic. This means it cannot be taken out by surgery or that it has spread to other parts of the body.

TAGRISSO can be prescribed for you if:

- You test positive for an 'EGFR exon 19 deletion mutation' or an 'EGFR exon 21 (L858R) substitution mutation' – for the initial treatment of your cancer. EGFR means Epidermal Growth Factor Receptor.
or
You test positive for an 'EGFR T790M mutation' – you may have been treated before with other EGFR inhibitor medicines.

How does TAGRISSO work?

TAGRISSO is a type of drug that targets EGFR sensitising mutations and T790M mutations and may help to slow or stop your lung cancer from growing. It may also help to shrink the tumour. TAGRISSO has been shown to produce effects on the tumour within 6 to 12 weeks of starting therapy. However, this may vary from patient to patient.

What are the ingredients in TAGRISSO?

Medicinal ingredient: osimertinib mesylate

Non-medicinal ingredients: black iron oxide, mannitol, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, macrogol, polyvinyl alcohol, red iron oxide, sodium stearyl fumarate, talc, titanium dioxide, and yellow iron oxide.

TAGRISSO comes in the following dosage forms:

Tablets, 40 and 80 mg.

Do not use TAGRISSO if:

- you are allergic to osimertinib or any of the other ingredients of TAGRISSO or the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TAGRISSO. Talk about any health conditions or problems you may have, including if you:

- have suffered from **interstitial lung disease (including pneumonitis)** which means that your lungs were inflamed or scarred.
- have ever had heart problems.
- have a family history of sudden cardiac death before 50 years of age.
- are dehydrated or suffer from excessive vomiting or eating disorders.
- have problems with your electrolytes such as low levels of potassium in the blood (hypokalemia), low levels of magnesium in the blood (hypomagnesemia) or low levels of calcium in the blood (hypocalcemia).
- have a history of fainting.
- have liver disease or kidney disease.
- have a history of eye problems.
- wear contact lenses.
- have any other medical conditions.

Other warnings you should know about:

- You will need to have your cancer tested to see if you have the EGFR T790M mutation before taking TAGRISSO.
- TAGRISSO should not be used in children and adolescents under 18 years of age.

Skin and nail problems can occur. You may get rash, dry skin, itching and problems with your nails. These are more likely in areas exposed to the sun. This can include **paronychia** which is red, hot, painful pus-filled blisters or swelling around the nail or an infection where

the nail and skin meet at the side or the base of a fingernail or toenail. Consider using moisturizers regularly on your skin and nails to help control these problems.

Eye problems can occur. You should tell your doctor right away if you get any symptoms of eye problems: eye pain, swelling, redness with a gritty feeling, watery eyes; blurred vision, sensitivity to light, sudden changes in your eyesight, or other eyesight changes. If left untreated, your eye problems may worsen and may lead to loss of eyesight. You may be at increased risk if you wear contact lenses.

Driving and using machines: Do not drive or use any tools or machines if you feel dizzy or get any symptoms that affect your eyesight, ability to concentrate or react.

Pregnancy, contraception and breastfeeding – information for women and men

Pregnancy – information for women

- You must not take TAGRISSO if you are pregnant. This is because it may harm your unborn baby.
- TAGRISSO can cause miscarriage.
- Do not get pregnant while taking TAGRISSO. If you are able to get pregnant, you must use effective birth control.
- If you get pregnant during treatment, tell your doctor immediately. Your doctor will decide with you if you should continue to take TAGRISSO.
- If you plan to get pregnant after taking the last dose of TAGRISSO, ask your doctor for advice. This is because TAGRISSO may remain in your body after the last dose.

Pregnancy – information for men

If your partner gets pregnant while you are taking TAGRISSO, tell her doctor right away.

Birth Control - information for women and men

You must use effective birth control during treatment.

TAGRISSO may change how well some birth control methods work. This includes “The Pill”. Talk to your doctor about the most appropriate methods of birth control. You may need to add a barrier method to your birth control.

Men taking TAGRISSO must use a condom because the drug may pass into the sperm. **After you finish treatment with TAGRISSO:**

- **Women** must keep using birth control for at least 2 months.
- **Men** must keep using birth control for at least 4 months.

Breastfeeding

Do not breastfeed while taking TAGRISSO. It may get into breast milk and harm your baby.

Tell your healthcare professional about all of the medicines you are taking, have recently taken or might take, including any drugs, vitamins, minerals, natural supplements or

alternative medicines. This is because TAGRISSO can affect the way some other medicines work. Also, some other medicines can affect the way TAGRISSO works. For example:

The following may interact with TAGRISSO in different ways:

Some drugs that may reduce how well TAGRISSO works:

- Phenytoin, carbamazepine or phenobarbital. They are used for seizures or fits.
- Rifabutin or rifampicin. They are used for tuberculosis (TB).
- St. John's Wort (*Hypericum perforatum*). It is an herbal medicine used for depression.

TAGRISSO may affect how well the following medicines work or may lead to increased side effects:

- Warfarin - used for blood clots
- Pimozide – used for mental illness
- Tizanidine – used as a muscle relaxant
- ‘Statin’ medicines such as rosuvastatin - used to lower cholesterol
- Oral hormonal birth control pill - used to prevent pregnancy
- Phenytoin and S-mephenytoin - used for seizures or fits
- Alfentanil, fentanyl and other painkillers - used for operations
- Ciclosporin, sirolimus and tacrolimus - used in transplant patients
- Daunorubicin, doxorubicin, paclitaxel and topotecan - used for cancer
- Migraine medicines called ‘ergot alkaloids’ (such as ergotamine or dihydroergotamine)
- Quinidine, digoxin, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, verapamil and diltiazem, procainamide, dronedarone, flecainide, propafenone - used for heart problems
- Loop, thiazide and related diuretics; laxatives and enemas; amphotericin B and high-dose corticosteroids - drugs that can change electrolyte levels

How to take TAGRISSO:

Always take this medicine exactly as your doctor or pharmacist has told you. Do not stop taking this medicine - talk to your doctor first. It is important to take this medicine **every day**, for as long as your doctor prescribes it for you. If you do not take this medicine as prescribed by your doctor, your cancer may grow again. Check with your doctor or pharmacist if you are not sure.

Take TAGRISSO:

- By mouth, with or without food, every day at about the same time.
- Swallow the tablet whole with water. Do NOT crush, split or chew the tablet.

If you have trouble swallowing the tablet, you can mix it in water:

- Put the tablet in a glass - do not crush, split or chew the tablet.
- Add 50 mL of non-carbonated, room temperature water - do not use any other liquids.
- Stir the water until the tablet breaks-up into very small pieces - the tablet will not completely dissolve.
- Drink the liquid immediately.

- To make sure you have taken all of the medicine, rinse the glass thoroughly with another 50 mL of water and drink it.

Usual Adult Dose: One 80 mg tablet every day in a single dose.

Reduced Adult Dose: If necessary, your doctor may reduce your dose to: One 40 mg tablet every day in a single dose.

Overdose:

If you think you have taken too much TAGRISSO contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if you do not have symptoms.

Missed Dose:

If you forget a dose, take it as soon as you remember it. However, if it is less than 12 hours until your next dose is due, skip the missed dose. Take your next normal dose at its scheduled time.

What are possible side effects from using TAGRISSO?

These are not all the possible side effects you may feel when taking TAGRISSO. If you experience any side effects not listed here, contact your healthcare professional. Please also see the Serious Warnings and Precautions Box above. Side effects may include:

- Decrease in appetite, sores inside the mouth
- Vomiting
- Headache, dizziness, decreased ability to concentrate or react
- Weakness, feeling tired
- Back pain
- Cough
- Nose or throat infection, runny or stuffy nose
- Nose bleeds
- Changes in eyesight

TAGRISSO can cause abnormal test results. Your doctor will decide when to do necessary tests. They include heart tests such as Echocardiogram and Electrocardiogram (ECG). Eye exams may be needed. Blood tests are needed before you start and while taking TAGRISSO. Your doctor will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON (≥10% of patients)			
Diarrhea that comes and goes: At least 3 loose liquid bowel movements a day.	√		
Nausea, Constipation	√		
Stomatitis: ulcer or sore, red and inflamed areas on the lips or inside the mouth.	√		
Decreased white blood cells (leukocytes, lymphocytes or neutrophils): infections, fatigue, fever, aches, pains, and flu-like symptoms.		√	
Decreased platelets: bruising, bleeding, fatigue, and weakness.		√	
Skin and nail problems: itching, dry skin, rash, redness. Paronychia (nail infection): red, hot, painful pus-filled blisters around the nail, with swelling. Detached, discoloured or abnormally shaped nails.		√	
COMMON (≥1% and <10% of patients)			
Lung problems (interstitial lung disease, pneumonitis, pneumonia): serious or suddenly worse shortness of breath, wheezing, tiredness, possibly with a cough or fever. Painful breathing. This can cause death in some cases.			√
Electrical problems with the heart (QT interval prolongation) that could lead to heart rhythm disturbances: fatigue, weakness, dizziness, fainting, being lightheaded or loss of consciousness, irregular heartbeat.			√
Heart failure and an enlarged heart (left ventricular dysfunction, cardiomyopathy and congestive heart failure): tiredness along with swollen ankles, shortness of breath especially when lying down.			√
Liver disorder, jaundice, toxicity, or failure: yellow skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Eye infection (conjunctivitis): itchy, red eyes with discharge, and swelling. Eye problems: trouble seeing, blurred vision, dry eye.		√	
Pulmonary embolism: shortness of breath, chest pain particularly upon breathing in, and coughing up blood.			√
Shortness of breath		√	
Acute respiratory failure: sudden worsening of shortness of breath, bluish colour on skin, lips, and fingernails, irregular heartbeats, feel sleepy, loss of consciousness.			√
UNCOMMON (≥0.1% and <1% of patients)			
Pulmonary edema (fluid in the air spaces of the lungs): difficult breathing that is worse when you lie down. Cough up blood or blood-tinged froth.		√	
Reduced kidney function: change in frequency of urination, pain when you urinate, nausea, vomiting, swelling of extremities, fatigue.	√		
Keratitis (red eye with a 'gritty' sensation): eye pain, eye swelling and redness, watery eyes, vision changes, and sensitivity to light.		√	
UNKNOWN			
Allergic reactions: itch, rash, hives, swelling of the lips, tongue or throat, difficulty swallowing or breathing.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by

- mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep TAGRISSO out of sight and reach of children.
- Do not use this medicine after the expiry date (EXP) which is stated on the blister foil and carton. The expiry date refers to the last day of that month.
- Keep TAGRISSO tablets at room temperature (15-30°C).
- Do not use any pack that is damaged or shows signs of tampering.

If you want more information about TAGRISSO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website at <http://www.canada.ca/en/health-canada.html>; the sponsor's website at www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: Questions or concerns - 1 (800) 668-6000
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

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