**Package leaflet: Information for the patient**

**TAGRISSO 40 mg film-coated tablets**
**TAGRISSO 80 mg film-coated tablets**
osimertinib

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What TAGRISSO is and what it is used for

TAGRISSO contains the active substance osimertinib, which belongs to a group of medicines called protein kinase inhibitors which are used to treat cancer. TAGRISSO is used to treat adults with a type of lung cancer called 'non-small cell lung cancer.' If a test has shown that your cancer has certain changes (mutations) in a gene called 'EGFR' (epidermal growth factor receptor) your cancer is likely to respond to treatment with TAGRISSO. TAGRISSO can be prescribed for you:

- after complete removal of your cancer as a post-surgical (adjuvant) treatment
  or
- as the first medicine you receive for your cancer which has spread to other parts of the body
  or
- in certain circumstances if you have been treated for your cancer before with other protein kinase inhibitor medicines.

**How TAGRISSO works**

TAGRISSO works by blocking EGFR and may help to slow or stop your lung cancer from growing. It may also help to reduce the size of the tumour and prevent the tumour from coming back after removal by surgery.

- If you are receiving TAGRISSO after complete removal of your cancer, it means that your cancer contained defects in the EGFR gene, 'exon 19 deletion' or 'exon 21 substitution mutation'.

- If TAGRISSO is the first protein kinase inhibitor medicine you are receiving, it means that your cancer contains defects in the EGFR gene, for example 'exon 19 deletion' or 'exon 21 substitution mutation'.

- If your cancer has progressed while you were being treated with other protein kinase inhibitor medicines, it means that your cancer contains a gene defect called 'T790M'. Because of this defect, other protein kinase medicines may no longer work.

If you have any questions about how this medicine works or why this medicine has been prescribed for you, ask your doctor.

## 2. What you need to know before you take TAGRISSO

**Do not take TAGRISSO if:**
- you are allergic (hypersensitive) to osimertinib or any of the other ingredients of this medicine (listed in section 6).
- you are taking St. John's Wort (Hypericum perforatum).

If you are not sure, talk to your doctor, pharmacist or nurse before taking TAGRISSO.

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before taking TAGRISSO if:
- you have suffered from inflammation of your lungs (a condition called 'interstitial lung disease').
- you have ever had heart problems – your doctor may want to keep a close eye on you.
- you have a history of eye problems.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking this medicine.

**Tell your doctor straight away while taking this medicine if:**
- you have sudden difficulty in breathing together with a cough or fever.
- you have severe peeling of your skin.
- you develop persistent fever, bruising or bleeding more easily, increasing tiredness, pale skin and infection.
  See 'Serious side effects' in section 4 for more information.

**Children and adolescents**
TAGRISSO has not been studied in children or adolescents. Do not give this medicine to children or adolescents under the age of 18 years.

**Other medicines and TAGRISSO**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription. This is because TAGRISSO can affect the way some other medicines work. Also some other medicines can affect the way TAGRISSO works.

**Tell your doctor before taking TAGRISSO if you are taking any of the following medicines:**

The following medicines may reduce how well TAGRISSO works:
- Phenytoin, carbamazepine or phenobarbital – used for seizures or fits.
- Rifabutin or rifampicin – used for tuberculosis (TB).
- St. John's Wort (Hypericum perforatum) – an herbal medicine used for depression.

TAGRISSO may affect how well the following medicines work and/or increase side effects of these medicines:
- Rosuvastatin – used to lower cholesterol.

- Oral hormonal contraceptive pill– used to prevent pregnancy.
- Bosentan – used for high blood pressure in the lungs.
- Efavirenz and etravirine – used to treat HIV infections/AIDS.
- Modafinil – used for sleep disorders.
- Dabigatran – used to prevent blood clots.
- Digoxin – used for irregular heart beat or other heart problems.
- Aliskiren – used for high blood pressure.

**If you are taking any of the medicines listed above, tell your doctor before taking TAGRISSO.**
Your doctor will discuss appropriate treatment options with you.

**Pregnancy – information for women**
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. If you do become pregnant during treatment, tell your doctor straight away. Your doctor will decide with you whether you should carry on taking TAGRISSO.
- You should not become pregnant while taking this medicine. If you are able to become pregnant, you must use effective contraception. See 'Contraception - information for women and men' below.
- If you plan to become pregnant after taking the last dose of this medicine, ask your doctor for advice. This is because some medicine may remain in your body, (see advice on contraception below).

**Pregnancy – information for men**
- If your partner becomes pregnant while you are taking this medicine, tell your doctor straight away.

**Contraception – information for women and men**
You must use effective contraception during treatment.
- TAGRISSO may interfere with how well oral hormonal contraceptives work. Discuss with your doctor the most appropriate methods of contraception.
- TAGRISSO may pass into semen. Therefore, it is important that men also use effective contraception.

You must also do this after completing treatment with TAGRISSO:
- **Women** – keep using contraception for 2 months after.
- **Men** – keep using contraception for 4 months after.

**Breast-feeding**
Do not breast-feed while taking this medicine. This is because it is not known if there is a risk to your baby.

**Driving and using machines**
TAGRISSO has no or no marked influence on the ability to drive and use machines.

**TAGRISSO contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

## 3. How to take TAGRISSO

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**How much to take**
- The recommended dose is one 80 mg tablet each day.
- If necessary, your doctor may reduce your dose to one 40 mg tablet each day.

**How to take**
- TAGRISSO is taken by mouth. Swallow the tablet whole with water. Do not crush, split or chew the tablet.
- Take TAGRISSO every day at the same time.
- You can take this medicine with or without food.

If you have trouble swallowing the tablet, you can mix it in water:
- Put the tablet in a glass.
- Add 50 mL (about two-thirds of a tumblerful) of still (non-fizzy) 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 straight away.
- To make sure you have taken all of the medicine, rinse the glass thoroughly with another 50 mL of water and drink it.

**If you take more TAGRISSO than you should**
If you take more than your normal dose, contact your doctor or nearest hospital straight away.

**If you forget to take TAGRISSO**
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.

**If you stop taking TAGRISSO**
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 have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**
Tell your doctor straight away if you notice the following serious side effects:
- Sudden difficulty in breathing together with a cough or fever - this may be a sign of inflamed lungs (a condition called ‘interstitial lung disease’). Most cases can be treated but some cases have been fatal. Your doctor may wish to stop TAGRISSO if you get this side effect. This side effect is common: it may affect up to 1 in 10 people.
- If you develop watery eyes, sensitivity to light, eye pain, eye redness, or vision changes. This side effect is uncommon: it may affect up to 1 in 100 people.
- Stevens-Johnson syndrome and toxic epidermal necrolysis, which can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and be preceded by fever and flu-like symptoms. Stevens-Johnson syndrome is rare: it may affect up to 1 in 1000 people. The frequency of toxic epidermal necrolysis cannot be determined as cases have only been reported since marketing TAGRISSO. See also Section 2.

- Changes in the electrical activity in the heart (QTc prolongation) such as rapid or irregular heartbeats, dizziness, light-headedness, chest discomfort, shortness of breath and fainting. This side effect is uncommon: it may affect up to 1 in 100 people.
- A blood disorder called aplastic anaemia, when bone marrow stops producing new blood cells – signs suggestive of this blood disorder may include persistent fever, bruising or bleeding more easily, increased tiredness and a decrease in your ability to fight infection. This side effect is rare: it may affect up to 1 in 1000 people.
- A condition in which the heart does not pump enough blood out of the heart in one beat as well as it should which could result in shortness of breath, tiredness and ankle swelling (suggestive of heart failure or left ventricular ejection fraction decreased).

Tell your doctor straight away if you notice the serious side effects listed above.

**Other side effects**
**Very common** (may affect more than 1 in 10 people)
- Diarrhoea - this may come and go during treatment. Tell your doctor if your diarrhoea does not go away or becomes severe.
- Skin and nail problems - signs may include pain, itching, dry skin, rash, redness around the fingernails. This is more likely in areas exposed to the sun. Using moisturisers regularly on your skin and nails can help with this. Tell your doctor if your skin or nail problems get worse.
- Stomatitis - inflammation of the inner lining of the mouth or ulcers forming in the mouth.
- Loss of appetite.
- Reduction in the number of white blood cells (leukocytes, lymphocytes or neutrophils).
- Reduction in the number of platelets in the blood.

**Common** (may affect up to 1 in 10 people)
- Increase of a substance in the blood called creatinine (produced by your body and removed by the kidney). These changes are usually mild in nature.
- Nose bleed – this is usually mild in nature.
- Hair thinning – this is usually mild in nature.
- Hives (urticaria) – itchy, raised patches anywhere on the skin, which may be pink or red and round in shape. Tell your doctor if you notice this side effect.
- Hand-foot syndrome – this may include redness, swelling, tingling or burning sensation with cracking of the skin on the palms of hands and/or soles of feet. These types of effects can usually be treated with creams and lotions.
- Increase of a substance in the blood called creatine phosphokinase (an enzyme released into the blood when muscle is damaged).

**Uncommon** (may affect up to 1 in 100 people)
- Skin greying or darkening (hyperpigmentation).
- Target lesions, which are skin reactions that look like rings (suggestive of Erythema multiforme). This side effect is uncommon: it may affect up to 1 in 100 people.
- Inflammation of the blood vessels in the skin. This may give the appearance of bruising or patches of non-blanching rash on the skin.

**Rare** (may affect up to 1 in 1000 people)
- Inflammation of the muscle which may result in muscle pain or weakness.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse.
This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow

Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store TAGRISSO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister foil and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if the pack is damaged or shows signs of tampering.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What TAGRISSO contains**

- The active substance is osimertinib (as mesylate). Each 40 mg film-coated tablet contains 40 mg of osimertinib. Each 80 mg film-coated tablet contains 80 mg of osimertinib.
- The other ingredients are mannitol, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, sodium stearyl fumarate, polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, yellow iron oxide, red iron oxide, black iron oxide (see section 2 “TAGRISSO contains sodium”).

**What TAGRISSO looks like and contents of the pack**
TAGRISSO 40 mg is supplied as beige, film-coated, round and biconvex tablets, marked with “AZ” and “40” on one side, and plain on the other.

TAGRISSO 80 mg is supplied as beige, film-coated, oval and biconvex tablets, marked with “AZ” and “80” on one side, and plain on the other.

TAGRISSO is supplied in blisters containing 30 x 1 film-coated tablets, packed in cartons containing 3 blisters of 10 tablets each.

TAGRISSO is supplied in blisters containing 28 x 1 film-coated tablets, packed in cartons containing 4 blisters of 7 tablets each.

**Marketing Authorisation Holder**

AstraZeneca UK Limited
1 Francis Crick Avenue,
Cambridge,
CB2 0AA
UK.

**Manufacturer**

AstraZeneca AB
Gärtunavägen
SE-152 57 Södertälje
Sweden

**This leaflet was last revised in February 2024.**



ONC 23 0014

**Other sources of information**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

| **Product name** | **Reference number** |
|---|---|
| Tagrisso 40 mg Tablets | 17901/0340 |
| Tagrisso 80 mg Tablets | 17901/0341 |

This is a service provided by the Royal National Institute of the Blind.