**Patient Information Leaflet**

TAGRISSO™ 40 MG TABLETS

TAGRISSO™ 80 MG TABLETS

osimertinib

Read this entire leaflet carefully before you start taking this medicine.

* 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

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# What TAGRISSO is and what it is used for:

**What TAGRISSO** **is:**

TAGRISSO is a medicine used to treat cancer. It contains the active substance osimertinib which belongs to the protein kinase inhibitor class of anticancer medicines.

**What TAGRISSO** **is used for :**

TAGRISSO is used to treat adults with a type of lung cancer called ‘non-small cell lung cancer.’ It is used when:

* You test positive for a ‘T790M mutation’ – see ‘How TAGRISSO works.’
* Your cancer is advanced and is worsening despite previous treatments, including a medicine which worked to block ‘EGFR’ (epidermal growth factor receptor).

**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.

**How TAGRISSO** **works:**

* A test has shown that your cancer is linked to a specific change in the EGFR gene called ‘T790M.’ This is known as a T790M mutation.
* Because of this T790M mutation, medicines that block EGFR may no longer work.
* TAGRISSO affects T790M and may help to slow or stop your lung cancer growing. It may also help to shrink the tumour.

TAGRISSO will only be prescribed to you by a doctor with experience in the use of medicines for cancer.

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

# Before you take TAGRISSO:

**Do not take TAGRISSO** **if:**

* you are allergic (hypersensitive) to osimertinib or any of the other ingredients of TAGRISSO (listed in section 6).
* you are taking St. John’s wort (Hypericum perforatum).

Do not take TAGRISSO if the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking TAGRISSO.

**Take special care with TAGRISSO if:**

Talk to your doctor, pharmacist or nurse before taking TAGRISSO if:

* you have suffered from inflammation of your lungs (called ‘interstitial lung disease’)
* you have ever had heart problems - your doctor may want to keep a close eye on you.

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

**Tell your doctor straight away while taking this medicine if:**

* you have sudden difficulty in breathing together with a cough or fever. See ‘Serious side effects’ in section 4 for more information.

**Taking other medicines, herbal or dietary supplements:**

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.

**TAGRISSO** **and other medicines for cancer:**

TAGRISSO has not been approved for use with other medicines for cancer.

**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) – a herbal medicine used for depression

TAGRISSO may affect how well the following medicines work and/or increase side effects of this medicine:

* Warfarin – used for blood clots
* Rosuvastatin - used to lower cholesterol.
* Oral hormonal contraceptive pill– used to prevent pregnancy
* Phenytoin and S-mephenytoin – used for seizures or fitsAlfentanil, fentanyl and other painkillers used for operations
* Bosentan – used for high blood pressure in the lungs.
* Efavirenz and etravirine – used to treat HIV infections/AIDS.
* Modafinil – used for sleep disorders.

**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, contraception and breast-feeding** – **information for women and men**

**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 TAGRISSO, 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 6 weeks 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 marked influence on the ability to drive and use machines.

# 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.
* Take TAGRISSO every day at about the same time.
* You can take TAGRISSO with or without food.

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 (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 do not take this medicine as prescribed by your doctor, your cancer may grow again.

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

# POSSIBLE SIDE EFFECTS:

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

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible

side effects not listed in this leaflet.

**Serious side effects:**

Tell your doctor straight away if you notice the following serious side effect:

* Sudden difficulty in breathing together with a cough or fever - this may be a sign of inflamed lungs called ‘interstitial lung disease’ and can be fatal in some cases. 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).

Tell your doctor straight away if you notice the serious side effect 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 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.
* Abnormal decrease in the number of white blood cells (leukocytes or neutrophils).
* Reduction in the number of platelets in the blood.

# HOW TO STORE TAGRISSO:

* Keep this medicine out of the sight and reach of children.
* Do not use this medicine after the expiry date (EXP) which is stated on blister foil and carton. The expiry date refers to the last day of that month.
* This medicine does not require any special storage conditions.
* Do not use any pack that 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.

# FURTHER 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 of osimertinib.
* The other ingredients are: mannitol, microcrystalline cellulose, low-substituted hydroxpropyl cellulose, sodium stearyl fumarate, polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, ferric oxide yellow, iron oxide, red iron oxide, black iron oxide.,

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 containing30x1 film-coated tablets, packed in cartons containing 3 blisters of 10 tablets each.

**Marketing Authorisation Holder:**

AstraZeneca AB

SE‑151 85, Södertälje

Sweden

**Manufacturer:**

AstraZeneca AB

SE-151 85 Södertälje

Sweden

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**To report any side effect(s):**

**• Saudi Arabia:**

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| **- National Pharmacovigilance Center (NPC):**   * **Fax: +966-11-205-7662** * **Call NPC at :**   **+966-11-2038222 Exts: 2317-2356-2353-2354-2334-2340**   * **Toll free phone: 8002490000** * **E-mail: npc.drug@sfda.gov.sa** * **Website: www.sfda.gov.sa/npc** |

**• Other GCC states:**

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| **- Please contact the relevant competent authority.** |

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| **THIS IS A MEDICAMENT**  **Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.**  **- The doctor and the pharmacist are the experts in medicines, their benefits and risks.**  **- Do not by yourself interrupt the period of treatment prescribed.**  **- Do not repeat the same prescription without consulting your doctor.**  **- Keep all medicaments out of reach of children.**  **Council of Arab Health Ministers, Union of Arab Pharmacists.** |

**TAGRISSO™** **is a trade mark of the AstraZeneca group of companies.**

**This patient information leaflet is approved by the Saudi Food and Drug Authority**