

# TAGRISSE<sup>®</sup> FILM-COATED TABLETS

Osimertinib (40mg & 80mg)

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## What TAGRISSE is used for

TAGRISSE contains the active substance osimertinib which belongs to a group of medicines called protein kinase inhibitors. TAGRISSE is used to treat adults with a type of lung cancer called 'non-small cell lung' when the tumour has a defect (mutation) in gene called EGFR (epidermal growth factor receptor).

TAGRISSE alone can be prescribed for you:

- If you test positive for an 'exon 19 deletion' or an 'exon 21 (L858R) substitution mutation'
  - to help prevent your lung cancer from coming back after your tumour(s) has been completely removed by surgery.
- If you test positive for an 'exon 19 deletion' or an 'exon 21 (L858R) substitution mutation'
  - as your first treatment when your lung cancer has progressed locally or spread to other parts of the body.
- If you test positive for a 'T790M mutation'
  - when your lung cancer has progressed locally or spread to other parts of the body, and you have had previous treatment with an EGFR tyrosine kinase inhibitor (TKI)

medicine that did not work or is no longer working.

- For a cancer that is unable to be removed (resected) by surgery and has responded or stabilised following treatment with chemotherapy and radiation.

TAGRISSE can be prescribed for you, in combination with other anti-cancer medicines, including:

- pemetrexed and a platinum-containing chemotherapy, as the first medicine you receive for your cancer which has progressed locally or spread to other parts of the body.

When TAGRISSE is given in combination with other anti-cancer medicines, it is important that you also read the package leaflet for these other medicines. If you have any questions about these medicines, ask your doctor.

## How TAGRISSE works

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

If you are receiving TAGRISSE for a cancer that is unable to be removed (resected) by surgery and has responded or stabilised following chemotherapy and radiation treatment, it means that your cancer contains defects in the EGFR gene, 'exon 19 deletion' or 'exon 21 substitution mutation'.

TAGRISSE 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 this medicine works or why this medicine has been prescribed for you, ask your doctor.

## Before you use TAGRISSE

### When you must not use it

Do not take TAGRISSE if:

- you are allergic (hypersensitive) to osimertinib or any of the other ingredients of this medicine.
- you are taking St. John's Wort (*Hypericum perforatum*).

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

### *Children and adolescents*

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

### Before you start to use it

Talk to your doctor, pharmacist or nurse before taking TAGRISSE 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 have rapid or irregular heartbeats, dizziness, light-headedness, chest discomfort, shortness of breath and fainting.
- you have watery eyes, sensitivity to light, eye pain,

eye redness or vision changes.

- you develop persistent fever, bruising or bleeding more easily, increasing tiredness, pale skin, and infection.

See 'Serious side effects' for more information.

#### Taking other medicines

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 medicine works 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 to treat 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.

#### **How to use TAGRISSO**

##### How much to use

- The recommended dose is one 80 mg tablet each day when TAGRISSO is taken alone.
- The recommended dose of TAGRISSO is one 80 mg tablet each day when taken with pemetrexed and a platinum-containing chemotherapy.
- If necessary, your doctor may reduce your dose to one 40 mg tablet each day.

##### When to use it

- 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.

##### How long to use it

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.

##### If you forget to use it

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 use too much (overdose)

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

#### **While you are using TAGRISSO**

##### Things you must do

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

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' for more information.

##### Things you must not do

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.

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

##### Things to be careful of

*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".

**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.
- 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 and toxic epidermal necrolysis is uncommon: it may affect up to 1 in 100 people.
- 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 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.
- 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.

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.
- Itchy skin (pruritus) - Using moisturisers regularly on your skin can help with this.
- 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 or ulcers forming in the mouth.
- Loss of appetite.

**Common** (may affect up to 1 in 10 people)

- Inflammation of the lungs caused by radiation therapy to the chest (Radiation Pneumonitis).

- Nose bleed (epistaxis).
- Hair thinning (alopecia).
- 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.
- Increase of a substance in the blood called creatinine (produced by your body and removed by the kidney).
- Reduction in the number of white blood cells (leukocytes, lymphocytes or neutrophils).
- Reduction in the number of platelets in the blood.

**Uncommon** (may affect up to 1 in 100 people)

- Target lesions, which are skin reactions that look like rings (suggestive of Erythema multiforme).
- Inflammation of the blood vessels in the skin. This may give the appearance of bruising or redness of the skin that does not fade in colour when pressed (non-blanching).
- Inflammation of the muscle which may result in muscle pain or weakness.
- Skin greying or darkening (hyperpigmentation).

The following side effects have been reported in a clinical trial with patients receiving TAGRISSO in combination with pemetrexed and a platinum-containing chemotherapy:

**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.
- Increase of a substance in the blood called creatinine (produced by your body and removed by the kidney).

**Common** (may affect up to 1 in 10 people)

- Nose bleed (epistaxis).
- Itchy skin (pruritus) - Using moisturisers regularly on your skin can help with this.
- Hair thinning (alopecia).
- Target lesions, which are skin reactions that look like rings (suggestive of Erythema multiforme).
- 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.
- Skin greying or darkening (hyperpigmentation).
- 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.
- Increase of a substance in the blood called creatine phosphokinase (an enzyme released into the blood when muscle is damaged).

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of TAGRISSO**

Storage

- 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 store above 30°C.

Disposal

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.

**Product Description**

What it looks like

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

**Ingredients**

***Active ingredient:***

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.

***Inactive ingredients:***

The other ingredient(s) 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 “TAGRISSO contains sodium” section)

**MAL number:**

40mg: MAL20172807AZ  
80mg: MAL20172808AZ

**Manufacturer**

AstraZeneca AB,  
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**Product Registration Holder**

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