TAGRISSO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TAGRISSO?

TAGRISSO contains the active ingredient osimertinib mesilate. TAGRISSO is used to treat adults with a type of cancer called 'non-small cell lung cancer' when the tumour has a defect (mutation) in a gene called EGFR (epidermal growth factor receptor).

For more information, see Section 1. Why am I using TAGRISSO? in the full CMI.

2. What should I know before I use TAGRISSO?

Do not use if you have ever had an allergic reaction to osimertinib mesilate, or any other similar medicines for example other tyrosine kinase inhibitors, or any of the ingredients listed at the end of this leaflet.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use TAGRISSO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TAGRISSO and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use TAGRISSO?

- The usual dose is one 80 mg tablet per day. Your doctor may however prescribe a different dose such as one 40 mg tablet.
- Continue taking TAGRISSO for as long as your doctor tells you.

More instructions can be found in Section 4. How do I use TAGRISSO? in the full CMI.

5. What should I know while using TAGRISSO?

Things you should do	• If you are about to be started on any new

	medicine, remind your doctor and pharmacist that you are taking TAGRISSO. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TAGRISSO. • Ensure you are using effective contraception (man or woman). Even if you stop treatment, you should continue to use effective contraception for at least a further 6 weeks if you are a woman and a further 4 months if you are a man.
Things you should not do	• Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop using this medicine even if you feel well.
Driving or using machines	• This medicine is not expected to affect your ability to drive a car or operate machinery, however, if symptoms

	occur that affect your ability to concentrate, do not drive or operate machinery until the effect subsides.
Looking after your medicine	• Keep your tablets in a cool, dry place where the temperature stays below 30°C. • Keep your tablets in the pack until it is time to take them.

For more information, see Section 5. What should I know while using TAGRISSO? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include diarrhoea, dry skin, skin greying or darkening, rash, pain and redness around the fingernails or hair thinning. However, some serious side effects may need medical attention. These include sudden difficulty in breathing with a cough or fever, sore or red eyes, light sensitivity, blurred vision, rapid or irregular heartbeats, chest discomfort, shortness of breath, fainting, persistent fever, bruising easily, increased tiredness, severe blistering or peeling of skin or skin reactions that look like rings, unexplained muscle pain or weakness, trouble moving arms or legs, dark tea-coloured urine or decreased urination.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

TAGRISSO®

Active ingredient: Osimertinib mesilate

Consumer Medicine Information (CMI)

This leaflet provides important information about using TAGRISSO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TAGRISSO.**

Where to find information in this leaflet:

1. Why am I using TAGRISSO?
2. What should I know before I use TAGRISSO?
3. What if I am taking other medicines?
4. How do I use TAGRISSO?
5. What should I know while using TAGRISSO?
6. Are there any side effects?
7. Product details

1. Why am I using TAGRISSO?

TAGRISSO contains the active ingredient osimertinib mesilate. TAGRISSO is a tyrosine kinase inhibitor (TKI). It works by stopping cancer cells with a defect (mutation) in a gene called EGFR (epidermal growth factor receptor) from growing and multiplying.

It may also help prevent the tumour from coming back after removal by surgery.

TAGRISSO is used to treat adults with a type of cancer called 'non-small cell lung cancer' when the tumour has an EGFR mutation. It may help to prevent your cancer from coming back after the tumour(s) have been removed by surgery. TAGRISSO may also help to slow or stop your cancer from growing following treatment with chemotherapy and radiation therapy or when your cancer is advanced and is worsening. TAGRISSO may be used alone or in combination with other anti-cancer medicines.

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

TAGRISSO can be prescribed for you if you test positive for EGFR mutation.

2. What should I know before I use TAGRISSO?

Warnings

Do not use TAGRISSO if:

- you are allergic to osimertinib mesilate, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can use this medicine.
- you are allergic to any other similar medicines for example other tyrosine kinase inhibitors.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Check with your doctor if you:

- have or have had inflamed lungs (called 'interstitial lung disease'), pneumonia or other lung problems.
- have or have had heart problems or risk factors for heart problems. Your doctor may wish to monitor your heart before and during TAGRISSO treatment.
- have any other medical conditions
- take any medicines for any other condition
- have a history of eye problems
- **use or want to use contact lenses while you are taking TAGRISSO.**
- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Do not take this medicine if you are pregnant or if you (male or female) are planning to have a baby.

It may affect your developing baby if you take it during pregnancy.

If you are a man, tell your doctor if you are planning to have a baby with your partner.

Your doctor can discuss with you the risks and benefits involved. Whether you are male or female, your doctor will advise you to use an effective contraception while taking TAGRISSO and for at least 6 weeks for woman and 4 months for men after stopping the medicine.

Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in TAGRISSO passes into breast milk. If it does, your baby may be affected.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

These include:

- antibiotics such as rifampicin for treating bacterial infections
- medicines for epilepsy such as phenytoin and carbamazepine
- St John's Wort for treating depression
- rosuvastatin, a medicine used to treat high cholesterol levels
- medicines used to prevent blood clots such as warfarin and dabigatran
- digoxin, a medicine used to treat heart problems
- aliskiren, a medicine used for high blood pressure
- bosentan, a medicine used to treat high blood pressure in the lungs
- efavirenz and etravirine, medicines used to treat HIV infections
- any medicine being used to treat your cancer.

These medicines may not work properly if you are taking TAGRISSO or they may affect how well TAGRISSO works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TAGRISSO.

4. How do I use TAGRISSO?

How much to take

- The usual dose is one 80 mg tablet per day. Your doctor may however prescribe a different dose such as one 40 mg tablet.
- **Follow all directions given to you by your doctor or pharmacist carefully.**
- **If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

When to take

- **Take your medicine at about the same time each day.** Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take this medicine before or after food.

How to take

- **Swallow the tablets whole with a full glass of water.** If you can swallow the tablet whole, do not split, crush or chew it. If you cannot swallow the tablet, it can be dispersed by stirring in about one quarter of a cup of water and then immediately swallowed (it will not completely dissolve). Once finished, swirl the same amount of water in the cup and swallow it to ensure that none of the dispersed tablet is missed.

How long to take

- **Continue taking your medicine for as long as your doctor tells you.** It is important to keep taking your medicine even if you feel well.

If you forget to use TAGRISSO

TAGRISSO should be used regularly at the same time each day. If you miss your dose at the usual time and it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to. If it is more than 12 hours until your next dose, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much TAGRISSO

If you think that you have used too much TAGRISSO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TAGRISSO?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TAGRISSO.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Ensure you are using effective contraception. Even if you stop treatment, you should continue to use effective contraception for at least a further 6 weeks if you are a woman and a further 4 months if you are a man.

If you become pregnant while you are taking this medicine or within 6 weeks of stopping this medicine, tell your doctor immediately.

If you are a man and your partner becomes pregnant while you are taking this medicine or within 4 months of stopping this medicine, tell your doctor immediately.

If you develop symptoms such as persistent fever, bruising or bleeding more easily, increasing tiredness and fatigue, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. For example, periodic tests may be done if you have had heart problems in the past.

Things you should not do

- Do not take TAGRISSO to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine even if you feel well.
- Do not lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TAGRISSO affects you. This medicine is not expected to affect your ability to drive a car or operate machinery, however, if symptoms occur that affect your ability to concentrate, do not drive or operate machinery until the effect subsides.

Looking after your medicine

- **Keep your tablets in the pack until it is time to take them**. If you take the tablets out of the pack they may not keep well.
- **Keep your tablets below 30°C.**

Store your tablets in a cool dry place away from moisture, heat or sunlight; for example, do not store them:

- **in the bathroom or near a sink, or**
- **in the car or on window sills.**

Keep your medicine where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you start feeling worse while you are taking TAGRISSO.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut-related: • diarrhoea. This may come and go during treatment. Tell your doctor if your diarrhoea does not go away or becomes severe. **Skin, nail and hair-related:** • itching, dry skin, rash, pain and redness around the fingernails.	**Speak to your doctor if you have any of these less serious side effects and they worry you, or if they do not go away or get worse.**

Less serious side effects	What to do
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. • hair thinning. • 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) **Infection-related:** • increased susceptibility to infection and/or symptoms of fever as this can be associated with a reduction in the number of white blood cells (leukocytes, lymphocytes or neutrophils).	

Less serious side effects	What to do
• 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 effect can usually be treated with creams and lotions. **Bleeding-related:** • bruising easily, blood when you go to the toilet, bleeding from a cut longer than normal, nose or gum bleeding, yellowing of skin and/ or eyes. This could mean your platelet count (number of cells in your blood that naturally cause it to clot) is too low and you may need blood tests. **Other:** • inflammation of the inner lining of the mouth and	

Less serious side effects	What to do
ulcers forming in the mouth.	

Serious side effects

Serious side effects	What to do
Breathing-related: • sudden difficulty in breathing with a cough or fever. This may be a sign of inflamed lungs called 'interstitial lung disease'. Most cases can be treated but some cases have been fatal. Your doctor may wish to stop treatment if you get this side effect. **Eyes-related:** • sore or inflamed (red or puffy) eyes, teary eyes, light sensitivity, blurred vision. **Heart-related:** • changes in the electrical activity in the heart (QTc prolongation) such as rapid or irregular	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
heartbeats, dizziness, light-headedness, chest discomfort, shortness of breath and fainting. **Skin-related:** • severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome and/or toxic epidermal necrolysis). • target lesions, which are skin reactions that look like rings (suggestive of erythema multiforme). • cutaneous vasculitis: inflammation of blood vessels in the skin, that can look like non-blanching (the color does not disappear when pressed) or bruise-like marks on the skin, some of which may be raised lumps. **Blood-related:** • aplastic anaemia (when bone marrow stops producing new blood	

Serious side effects	What to do
cells): Symptoms such as persistent fever, bruising or bleeding more easily, increased tiredness and a decrease in your ability to fight infection. **Skeletal muscle-related:** • unexplained muscle pain, tenderness, weakness, or trouble moving arms or legs. • dark tea-coloured urine or decreased urination.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress. These tests could show a change, kidney, levels of blood cells or other changes.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TAGRISSO contains

Active ingredient (main ingredient)	osimertinib mesilate
Other ingredients (inactive ingredients)	• mannitol • microcrystalline cellulose • polyvinyl alcohol • hyprolose • sodium stearyl fumarate • titanium dioxide • purified talc • iron oxide black • iron oxide red • iron oxide yellow • macrogol 3350

Do not take this medicine if you are allergic to any of these ingredients.

What TAGRISSO looks like

There are 2 tablet strengths:

TAGRISSO 40 mg tablets are round, beige, coated tablets approximately 9 mm wide. The tablets have ‘AZ’ and ‘40’ on one side. (AUST R 255493)

TAGRISSO 80 mg tablets are oval, beige, coated tablets measuring approximately 7.25 × 14.5 mm. The tablets have ‘AZ 80’ on one side. (AUST R 255492)

TAGRISSO tablets are packed into aluminium blister strips in cartons of 30 tablets.

Who distributes TAGRISSO

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

This leaflet was prepared in August 2026.

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