

Tagrisso[®]

Osimertinib mesilate 40 and 80 mg Tablets.

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Tagrisso**. It does not contain all the information that is known about **Tagrisso**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Tagrisso** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Tagrisso is used for

This medicine 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). It is used to help prevent your cancer from coming back after the tumour(s) have been removed by surgery or when your cancer is advanced and is worsening. **Tagrisso** may be used alone or in combination with other anti-cancer medicines. **Tagrisso** can be prescribed for you if you test positive for EGFR mutation.

This medicine belongs to a class of medicines called Tyrosine Kinase Inhibitors (TKIs). It works by stopping cancer cells with the EGFR mutation from growing and multiplying. It may also help prevent the tumour from coming back after removal by surgery. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Tagrisso is available only with a doctor's prescription.

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.

Before you use Tagrisso

When you must not take it

Do not take **Tagrisso** if you have an allergy to:

- any of the ingredients listed at the end of this leaflet
- 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.

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. Your doctor will advise men and women to ensure they are using effective contraception when taking the medicine 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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- inflamed lungs (called 'interstitial lung disease'), pneumonia or other lung problems
- heart problems or risk factors for heart problems. Your doctor may wish to monitor your heart before and during **Tagrisso** treatment
- a history of eye problems.

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

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 form of contraception while taking **Tagrisso** and for at least 6 weeks for women and 4 months for men after stopping treatment.

If you have not told your doctor about any of the above, tell them before you start taking **Tagrisso**.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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
- rosuvastatin, a medicine used to treat high cholesterol levels
- warfarin, a medicine used to prevent blood clots
- efavirenz and etravirine, medicines used to treat HIV infections
- dabigatran – used to prevent blood clots
- aliskiren – used to for high blood pressure
- digoxin – used to treat irregular heart beat or other heart problems
- St John's Wort for treating depression
- 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. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Tagrisso

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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.

How to take it

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.

When to take it

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 long to take it

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 take it

If 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. Otherwise, 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 that 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 take too much (overdose)

Please telephone your doctor or the National Poisons Information Centre on 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much **Tagrisso**, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Tagrisso

Things you must do

If you are about to start 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 must 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.

Things to be careful of

Be careful driving or operating machinery until you know how **Tagrisso** affects you.

Side Effects

Tell your doctor or pharmacist as soon as possible if you start feeling worse while you are taking Tagrisso. This medicine helps the majority of people with your type of cancer, but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following:

- 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.
- sore or inflamed (red or puffy) eyes, teary eyes, light sensitivity, blurred vision.
- severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome or toxic epidermal necrolysis).
- target lesions, which are skin reactions that look like rings (suggestive of erythema multiforme).
- persistent fever, bruising or bleeding more easily, increased tiredness and a decrease in your ability to fight infection (suggestive of aplastic anaemia when bone marrow stops producing new blood cells).
- 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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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, pain and 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
- 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)
- inflammation of the inner lining of the mouth or ulcers forming in the mouth
- 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.
- increase of a substance in the blood called creatinine (produced by the body and removed by the kidney)
- hair thinning
- 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.
- Skin greying or darkening (hyperpigmentation)
- Hives (urticaria) – itchy, raised patches anywhere on the skin, which may be pink or red and round in shape.

- Abnormal blood test results to blood creatine phosphokinase (an enzyme released into the blood when muscle is damaged)

The above list includes the more common side effects of your medicine. They are usually mild and short-lived. **Tell your doctor or pharmacist if you notice anything that is making you feel unwell.** Other side effects not listed above may also occur in some people.

After using Tagrisso

Storage

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 in a cool dry place where the temperature stays below 30°C. Do not store **Tagrisso** or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

There are 2 tablet strengths:

- 40 mg strength tablets are round, beige, coated tablets approximately 9 mm wide. The tablets have 'AZ' and '40' on one side.
- 80 mg strength tablets are oval, beige, coated tablets measuring approximately 7.25 × 14.5 mm. The tablets have 'AZ 80' on one side.

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

Ingredients

Tagrisso contains 40 mg or 80 mg of osimertinib (as osimertinib mesilate) as the active ingredient.

Other ingredients include:

- mannitol
- microcrystalline cellulose
- polyvinyl alcohol
- hydroxypropylcellulose
- sodium stearyl fumarate
- titanium dioxide
- talc
- iron oxide black
- iron oxide red
- iron oxide yellow
- macrogol 3350.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Marketed by

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