PATIENT INFORMATION LEAFELET

SHEDULING STATUS: S4

TAGRISSO 40 mg Film-coated tablets

TAGRISSO 80 mg Film-coated tablets

Osimertinib

Sugar-free

Read all of this leaflet carefully before you start taking TAGRISSO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TAGRISSO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TAGRISSO is and what it is used for
2. What you need to know before you take TAGRISSO
3. How to take TAGRISSO
4. Possible side effects
5. How to store TAGRISSO
6. Contents of the pack and other information

1. What TAGRISSO is and what it is used for

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**.**

TAGRISSO is used to treat adults with a type of lung 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 when your cancer is advanced and is worsening.

TAGRISSO can be prescribed for you:

- after complete removal of your cancer as a post-surgical (adjuvant) treatment.

  or

- if you test positive for an ‘exon 19 deletion’ or an ‘exon 21 (L858R) substitution mutation’ for the initial treatment of your cancer.

  or

- you test positive for a “T790M mutation” you may have been treated before with other protein kinase inhibitor medicines.

2. What you need to know before you take TAGRISSO

Do not take TAGRISSO:

- if you are hypersensitive (allergic) to osimertinib or any of the other ingredients of TAGRISSO (listed in section 6)
- if you are pregnant or breastfeeding
- if you are taking St. John’s Wort

Warnings and precautions

Special care should be taken with TAGRISSO:

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

TAGRISSO may cause severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome).

Tell your doctor straight away while taking this medicine if:

- 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.

Other medicines and TAGRISSO

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

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

The following medicines may reduce how well TAGRISSO works:

- Phenytoin, carbamazepine or phenobarbitone – 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 fits.
- Alfentanil, 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.

TAGRISSO with food and drinking

You can take TAGRISSO with or without food.

Pregnancy and breastfeeding

TAGRISSO should not be taken during pregnancy and breastfeeding.

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 using this medicine 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.

Pregnancy

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking TAGRISSO. If you do become pregnant during treatment, tell your doctor immediately. Your doctor will decide with you whether you should carry on taking TAGRISSO.

Breastfeeding

Do not breastfeed while taking TAGRISSO.

Driving and using machines

If you experience symptoms affecting your ability to concentrate and react, it is recommended that you do not drive or use machines until the effect subsides.

3. How to take TAGRISSO

Do not share medicines prescribed for you with any other person.

Always take TAGRISSO exactly as your doctor or has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one 80 mg tablet taken daily. If necessary, your doctor may reduce your dose to one 40 mg tablet taken daily.

Your doctor will tell you how long your treatment with TAGRISSO will last. If you have the impression that the effect of TAGRISSO is too strong or too weak, tell your doctor or pharmacist.

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 tablets than your normal dose, contact your doctor or nearest hospital immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 TAGRISSO - talk to your doctor first. It is important to take TAGRISSO every day, for as long as your doctor prescribes it for you. If you do not take TAGRISSO as prescribed by your doctor, your cancer may grow again.

4. Possible side effects

TAGRISSO can have side effects.

Not all side effects reported for TAGRISSO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TAGRISSO, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- if you have sudden difficulty in breathing together 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.
- Stevens-Johnson syndrome, 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. This side effect is rare: it may affect up to 1 in 1000 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 uncommon: it may affect up to 1 in 100 people.
- if you develop watery eyes, sensitivity to light, eye pain, eye redness, or vision changes.

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea (passing of frequent, watery stools)
- skin and nail problems - signs may include itching, dry skin, rash, redness around the fingernails
- 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
- 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.
- 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).

Less frequent side effects:

- 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s

publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TAGRISSO.

5. How to store TAGRISSO

Store all medicines out of reach of children.

Store at or below 30 ^{o} C.

Keep the container in the outer container.

Do not use after the expiry date stated on the blister / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TAGRISSO contains

The active substance is osimertinib.

Each TAGRISSO 40 mg film-coated tablet contains 40 mg osimertinib as osimertinib mesylate.

Each TAGRISSO 80 mg film-coated tablet contains 80 mg osimertinib as osimertinib mesylate.

The other ingredients are black iron oxide, low substituted hydroxpropyl cellulose, macrogol 3350, mannitol, microcrystalline cellulose, polyvinyl alcohol, red iron oxide, sodium stearyl fumarate, talc, titanium dioxide, yellow iron oxide.

What TAGRISSO looks like and contents of the pack

TAGRISSO 40 mg: beige coloured, film-coated, round and biconvex tablets, marked with ‘AZ” and “40” on one side, and plain on the other.

TAGRISSO 80 mg: beige coloured, film-coated, round and biconvex tablets, marked with ‘AZ” and “80” on one side, and plain on the other.

TAGRISSO 40 mg tablets are packed in silver aluminium/aluminium blisters containing 30 film-coated tablets, in a carton (3 blisters of 10 tablets each)

TAGRISSO 80 mg tablets are packed in silver aluminium/aluminium blisters containing 30 film-coated tablets, in a carton (3 blisters of 10 tablets each)

Holder of certificate of registration

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This leaflet was last revised in

07 July 2023

Registration Numbers

TAGRISSO 40 mg: 51/26/0927

TAGRISSO 80 mg: 51/26/0928