PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TYREC 25 film-coated tablets

TYREC 100 film-coated tablets

TYREC 150 film-coated tablets

Erlotinib

Contains sugar: lactose monohydrate

Read all of this leaflet carefully before you start taking TYREC

- 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.
- TYREC 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 TYREC is and what it is used for

TYREC is a medicine used to treat cancer by preventing the activity of a protein called epidermal growth factor receptor (EGFR). This protein is known to be involved in the growth and spread of cancer cells.

TYREC can be prescribed to you if you have non-small cell lung cancer at an advanced stage. It can be prescribed as initial therapy, or as maintenance therapy if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

TYREC can also be prescribed to you in combination with another treatment called gemcitabine if you have cancer of the pancreas at a metastatic stage.

2. What you need to know before you take TYREC

Do not take TYREC:

- If you are hypersensitive (allergic) to erlotinib or any of the other ingredients of TYREC (listed in section 6).

Warnings and precautions

Special care should be taken with TYREC, and you should tell your doctor:

- If you have sudden difficulty in breathing associated with cough or fever because your doctor may need to treat you with other medicines and interrupt your TYREC treatment.
- If you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal (for example loperamide).
- if you have severe or persistent diarrhoea, nausea, loss of appetite, or vomiting because your doctor may need to interrupt your TYREC treatment and may need to treat you in the hospital.
- If you have severe pain in the abdomen.

- If you have severe blistering or peeling of skin. Your doctor may need to interrupt or stop your TYREC treatment.
- When you develop acute or worsening eye problems, for example, redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, please tell your doctor or nurse immediately as you may need urgent treatment.
- If you use contact lenses and/or have a history of eye problems such as severe dry eyes, inflammation of the front part of the eye (cornea) or ulcers involving the front part of the eye.
- If you smoke, you are advised to stop smoking if you are treated with TYREC, as smoking could decrease the amount of TYREC in your blood
- If you use any antacids, you need to discuss it with your doctor.

Children and adolescents

The safety of TYREC has not been established in patients under the age of 18 years, therefore treatment with TYREC is not recommended for children and adolescents.

Other medicines and TYREC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Take special care with TYREC:

- if you are taking other medicines that may increase or decrease the amount of erlotinib in your blood or influence its effect (for example ciprofloxacin, ciclosporin, verapamil, omeprazole, or ranitidine).
- if you are taking other medicines which may speed up or slow down the breakdown of TYREC (for example antifungals like ketoconazole, protease inhibitors, erythromycin, clarithromycin, rifampicin, phenytoin, carbamazepine,

barbiturates, St. John's Wort (*hypericum perforatum*) or proteasome inhibitors).

- if you are taking anticoagulants (a medicine which helps to prevent thrombosis or blood clotting e.g. warfarin), TYREC may increase your tendency to bleed. Talk to your doctor, he will need to regularly monitor you with some blood tests.
- if you are taking statins (medicines to lower your blood cholesterol), TYREC may increase the risk of statin related muscle problems, which on rare occasions can lead to serious muscle breakdown.

In some cases, these medicines may reduce the efficacy or increase the side effects of TYREC, and your doctor may need to adjust your treatment. Your doctor might avoid treating you with some of these medicines while you are receiving TYREC.

Your doctor will treat you with caution if you have a glucuronidation disorder like Gilbert's syndrome, as it can affect your liver and enzymes in your body, causing jaundice (yellowing of the skin and whites of the eyes).

It is not known whether TYREC has a different effect if your liver or kidneys are not functioning normally. The treatment with TYREC is not recommended if you have a severe liver disease or severe kidney disease.

TYREC with food and drink

Do not take TYREC with food. Take at least one hour before or two hours after you have eaten. See also section 3 "How to take TYREC".

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking TYREC.

Avoid pregnancy while being treated with TYREC. If you can become pregnant, use adequate contraception during treatment, and for at least 2 weeks after taking the last tablet. If you become pregnant while on treatment with TYREC, immediately inform your doctor who will decide if treatment should be continued. Do not breastfeed your baby while taking TYREC, and for at least 2 weeks after taking the last tablet.

Driving and using machines

It is not always possible to predict to what extent TYREC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TYREC affects them. TYREC is very unlikely to affect your ability to drive and use machines.

TYREC contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TYREC.

TYREC may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take TYREC

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

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

The TYREC tablet should be taken at least one hour before you eat or two hours after you have eaten.

Non-small cell lung cancer

The usual dose is one tablet of TYREC 150 mg each day.

Metastatic pancreatic cancer

The usual dose is one tablet of TYREC 100 mg each day and it is given in combination with gemcitabine treatment.

Your doctor will tell you how long your treatment with TYREC will last. Do not stop treatment early. If you have the impression that the effect of TYREC is too strong or too weak, tell your doctor or pharmacist.

Your doctor may adjust your dose in 50 mg steps. For the different dose regimens TYREC is available in strengths of 25 mg, 100 mg, or 150 mg.

If you take more TYREC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. You may have increased side effects and your doctor may interrupt your TYREC treatment.

If you forget to take TYREC

If you miss a dose of TYREC, contact your doctor or pharmacist as soon as possible. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TYREC

It is important to keep taking TYREC every day, as long as your doctor prescribes it for you. If you have any further questions on the use of TYREC, ask your doctor or pharmacist.

4. Possible side effects

TYREC can have side effects.

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

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

- A serious side effect is a form of lung irritation called interstitial lung disease. This disease can have a fatal outcome in some cases. If you develop symptoms such as sudden difficulty in breathing associated with cough or fever, contact your doctor immediately as you could suffer from this disease. Your doctor may decide to permanently stop your treatment with TYREC.
- Diarrhoea and vomiting. Persistent and severe diarrhoea may lead to low blood potassium and impairment of your kidney function, particularly if you receive other chemotherapy treatments at the same time. If you experience more severe or persistent diarrhoea contact your doctor immediately as your doctor may need to treat you in the hospital.

These are all very serious side effects. If you have them, you may have had a serious reaction to TYREC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you have severe pain in your abdomen, gastrointestinal perforations have been observed. Also, tell your doctor if you had peptic ulcers or diverticular disease in the past, as this may increase this risk.
- If your blood tests indicate severe changes in your liver function, your doctor may need to interrupt your treatment.
- If you notice a rash which may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sunscreen may be advisable.
- If you develop severe blistering or peeling of skin (suggestive of Stevens-

Johnson syndrome)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- infection
- loss of appetite, decreased weight
- depression
- headache, altered skin sensation or numbness in the extremities
- eye irritation
- difficulty in breathing, cough
- stomach pain
- indigestion
- flatulence
- nausea, vomiting
- bleeding from the stomach or the intestines
- rash
- itching, dry skin and loss of hair
- tiredness, fever, rigors (a chill, usually with shivering, as at the onset of high fever)
- bleeding from the nose
- acne, infection of hair follicles

Less frequent

- eyelash - or eyebrow changes
- cases of perforation or ulceration of the cornea
- inflammation of the coloured part of the eye

- excess body and facial hair
- brittle and loose nails
- flushed or painful palms or sole

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions 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 TYREC.

5. How to store TYREC

Store all medicines out of reach of children.

- Store at or below 25 °C
- 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 TYREC contains

- The active substance is erlotinib.

  Each TYREC 25 film-coated tablet contains 27,3 mg erlotinib hydrochloride equivalent to 25 mg of erlotinib.

Contains sugar: 17,5 mg lactose monohydrate per film-coated tablet.

Each TYREC 100 film-coated tablet contains 109,3 mg erlotinib hydrochloride equivalent to 100 mg of erlotinib.

Contains sugar: 70 mg lactose monohydrate per film-coated tablet.

Each TYREC 150 mg film-coated tablet contains 163,9 mg erlotinib hydrochloride equivalent to 150 mg of erlotinib.

Contains sugar: 105 mg lactose monohydrate per film-coated tablet.

- The other ingredients are hydroxypropyl cellulose, hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate and titanium dioxide.

What TYREC looks like and contents of the pack

TYREC 25 mg film-coated tablets: White to off white round, biconvex, film-coated tablets, debossed with "S13" on one side and plain on other side, packed in clear PVC – Aluminium foil blister pack, containing 10 film-coated tablets, in an outer carton.

TYREC 100 mg film-coated tablets: White to off white round, biconvex, film-coated tablets, debossed with "S12" on one side and plain on other side, packed in clear PVC – Aluminium foil blister pack, containing 10 film-coated tablets, in an outer carton.

TYREC 150 mg film-coated tablets: White to off white round, biconvex, film-coated tablets, debossed with "S11" on one side and plain on other side, packed in clear PVC – Aluminium foil blister pack, containing 10 film-coated tablets, in an outer carton.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

106, 16th Road

Midrand

This leaflet was last revised in

Registration numbers

TYREC 25 550660

TYREC 100 550661

TYREC 150 550662