PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Tarceva 25 mg tablets

Tarceva 100 mg tablets

Tarceva 150 mg tablets

Erlotinib

Contains sugar, i.e. lactose monohydrate.

Read all of this leaflet carefully before you start using this Tarceva

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Tarceva 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 Tarceva is and what it is used for
2. What you need to know before you are take Tarceva
3. How to take Tarceva
4. Possible side effects
5. How to store Tarceva
6. Contents of the pack and other information

1. What Tarceva is and what it is used for

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

Tarceva can be prescribed to you if you have adenocarcinoma of your lung.

It can be prescribed as initial therapy if your cancer cells have specific EGFR mutations. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with EGFR-negative tumours. It can also be prescribed either if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease. Tarceva 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 Tarceva

Do not use Tarceva:

- if you are allergic (hypersensitive) to erlotinib or any of the ingredients of Tarceva.
- If you have a history of or hereditary galactose intolerance e.g. galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption.

Warnings and precautions

Take special care with Tarceva:

- if you are taking other medicines because they may speed up or slow down the breakdown of Tarceva (for example antifungals such as ketoconazole, protease inhibitors, erythromycin, clarithromycin, phenytoin, carbamazepine, barbiturates, rifampicin, ciprofloxacin, omeprazole, ranitidine or St John's Wort). In some cases these medicines may reduce the efficacy or increase the side effects of Tarceva and your doctor may need to adjust your treatment.
- If you take blood thinners, warfarin, because Tarceva may increase your risk of bleeding and your doctor will need to regularly monitor you with blood tests.
- If you have a history of intolerance to sugars, or hereditary galactose intolerance e.g. galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption, as Tarceva contains lactose.

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 Tarceva treatment.
- If you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal medicines (for example loperamide).
- Immediately, if you have severe or persistent diarrhoea, nausea, loss of appetite or vomiting because your doctor may need to interrupt your Tarceva treatment and may need to treat you in the hospital.
- if you have severe pain in the abdomen, severe blistering or peeling of skin, or acute or worsening eye problems (for example eye pain). Your doctor may need to interrupt or stop your treatment.

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

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

You are advised to stop smoking if you are treated with Tarceva as smoking considerably decreases the amount of Tarceva available in your blood.

Children and adolescents: Tarceva safety has not been established in patients under the age of 18 years. Therefore treatment with Tarceva is not recommended for children and adolescents.

Other medicines and Tarceva

Taking other medicines with Tarceva:

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

Taking Tarceva with food and drink

Do not take Tarceva with food. See also section 3 "How to take Tarceva".

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor or pharmacist for advice before taking Tarceva.

Avoid pregnancy while being treated with Tarceva. 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 Tarceva, immediately inform your doctor who will decide if treatment should be continued. Do not breastfeed your baby while taking Tarceva.

Driving and using machines

Tarceva is very unlikely to affect your ability to drive and use machines.

Important information about some of the ingredients of Tarceva:

If you have a history of intolerance to sugars, or hereditary galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, as Tarceva contains lactose. Speak to your healthcare professional before you take Tarceva, they will advise you as to whether or not it is safe for you to take this medicine.

3. How to take Tarceva

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

Always take Tarceva exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

Non-small cell lung cancer: The usual dose is one 150 mg Tarceva tablet each day.

Pancreatic cancer: The usual dose is one tablet of Tarceva 100 mg each day. Tarceva is given in combination with gemcitabine treatment.

Your doctor will tell you how long your treatment with Tarceva will last. Do not stop treatment early.

If you have the impression that the effect of Tarceva is too strong or too weak, talk to your doctor or pharmacist.

Do not take Tarceva with a meal. Take your Tarceva tablet at least 1 hour before you eat or at least 2 hours after you have eaten. Swallow your tablet with a glass of plain water.

Your doctor may adjust your dose in 50 mg steps. For different dosage regimens, Tarceva is available in strengths of 25 mg, 100 and 150 mg.

If you take more Tarceva than you should:

In the event of overdosage contact your doctor or pharmacist immediately. You may have increased side effects and your doctor may interrupt your Tarceva treatment.

If you forget to take Tarceva:

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 Tarceva:

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

4. Possible side effects

Tarceva can cause side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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 Tarceva.

Frequent side effects

- rash
- diarrhoea
- itching, dry skin
- loss of hair
- eye irritation

- loss of appetite
- decreased weight
- nausea
- vomiting
- mouth irritation
- stomach pain
- indigestion
- flatulence
- tiredness
- fever
- rigors (a chill, usually with shivering, as at the onset of high fever)
- difficulty in breathing
- cough
- infection
- headache
- altered skin sensation or numbness in the extremities
- depression
- abnormal blood tests for the liver function
- bleeding from the stomach or the intestines
- bleeding from the nose can occur

Less frequent side effects

- liver failure can be observed. If your blood tests indicate severe changes in your liver function, your doctor may need to interrupt your treatment.
- persistent and severe diarrhoea may lead to low blood potassium and kidney failure, 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.

- rash may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sun screen (e.g. mineral-containing) may be advisable.

Contact your doctor as soon as possible if you suffer from any of the above side effects. In some cases your doctor may need to reduce your dose of Tarceva or interrupt treatment.

- hair and nail changes have been observed. These cases were mostly non-serious. They included inflammatory reactions around the fingernail (common), excess body and facial hair of a male distribution pattern (uncommon), eyelash and eyebrow changes (uncommon), and brittle and loose nails (uncommon). Uveitis, which is inflammation of the uvea of the eye (very rare).
- gastrointestinal perforations have been observed. Tell your doctor if you have severe pain in your abdomen. Also, tell your doctor if you had peptic ulcers or diverticular disease in the past, as this may increase this risk.

The following other side effects have been observed:

- ulceration or perforation of the cornea
- severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome).

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 nurse. This includes any possible side effects not listed in this leaflet. 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 Tarceva.

5. How to store Tarceva

Store all medicines out of the reach and sight of children. Do not use Tarceva after the expiry date on the pack. Do not store above 30 °C.

6. Contents of the pack and other information

What Tarceva contains

- The active substance is erlotinib.

The other ingredients are: Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, sodium lauryl sulphate, magnesium stearate, hydroxypropylcellulose, titanium dioxide, polyethylene glycol and hydroxypropyl methyl cellulose.

What Tarceva looks like and contents of the pack

Tarceva 25 mg Tablets: White to yellowish, round, biconvex tablets with 'T25' engraved on one side. PVC blisters containing 30 tablets per pack.

Tarceva 100 mg Tablets: White to yellowish, round, biconvex tablets with 'T100' engraved on one side. PVC blisters containing 30 tablets per pack.

Tarceva 150 mg Tablets: White to yellowish, round, biconvex tablets with 'T150' engraved on one side. Tarceva 150 mg: PVC blisters containing 30 tablets per pack.

Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park,

Building E, Vorna Valley, Midrand

Johannesburg, 1686

South Africa

Roche Ethical Assistance Line toll-free: 0800 21 21 25

This leaflet was last revised in 07 March 2022

Registration numbers

Tarceva® 25 mg tablets	A40/26/0359
Tarceva® 100 mg tablets	A40/26/0360
Tarceva® 150 mg tablets	A40/26/0361