

TARCEVA®

contains the active ingredient erlotinib



Patient Information Leaflet

What is in this leaflet

1. What Tarceva is used for
2. How Tarceva works
3. Before you take Tarceva
4. How to take Tarceva
5. While you are using Tarceva
6. Side effects
7. After using Tarceva
8. Product Description
9. Manufacturer

1. What Tarceva is used for

Tarceva contains the active ingredient erlotinib.

Tarceva is indicated for adults. This medicine can be prescribed to you if you have non-small cell lung cancer at an advanced stage. It can be prescribed as initial therapy if your cancer cells have specific EGFR mutations. It can also be prescribed if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

TARCEVA is also used in combination with gemcitabine for the treatment of pancreatic cancer.

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

2. How Tarceva works

As a targeted cancer treatment, Tarceva targets a specific protein on the surface of the cancer cells called EGFR/ HER1 (epidermal growth factor receptor 1). It slows or blocks the activity of EGFR and may cause the cancer cells to die, with potentially less

damage to normal cells. However, the way Tarceva works to treat cancer is not fully known.

3. Before you take Tarceva

When you must not take it

Do not take Tarceva if:

1. you have had an allergic reaction to Tarceva or any ingredients listed at the end of this leaflet
2. the package is torn or shows signs of tampering
3. the expiry date (EXP) printed on the pack has passed

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking Tarceva, talk to your doctor.

Use in children

Do not give Tarceva to children.

Safety and effectiveness in patients less than 18 years of age have not been established.

Before you start to take it

Your doctor must know about all the following before you start to take Tarceva.

Tell your doctor if:

1. you are pregnant or plan to become pregnant

Tarceva may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Tarceva while you are pregnant.

If you are a woman who could become pregnant use

adequate contraception during treatment, and for at least 2 weeks after taking the last tablet.

If you become pregnant while you are being treated with Tarceva, tell your doctor immediately.

2. you are breast-feeding or plan to breast-feed

It is not known whether erlotinib passes into breast milk. It is not recommended that you breast-feed while taking Tarceva.

3. you have liver problems

It is not known whether Tarceva has a different effect if your liver is not functioning normally.

4. you have kidney problems

5. you have a history of stomach ulcers or inflammation of the bowel wall

6. you are allergic to any other medicines, foods, dyes or preservatives

7. you cannot tolerate lactose

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

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with Tarceva. These medicines include:

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- antacids, medicines used to treat heartburn and indigestion
- ciprofloxacin, a medicine used to treat bacterial infection
- corticosteroids, a group of medicines used to treat inflammation
- erythromycin, a medicine used to treat bacterial infection
- H₂ antagonists, a group of medicines used to treat stomach ulcers or reflux
- ketoconazole, a medicine used to treat fungal infection
- midazolam, a medicine used to induce drowsiness before an operation
- non-steroidal anti-inflammatory medicines (NSAIDs), a group of medicines commonly used as pain killers
- statins, a group of medicines used to lower cholesterol
- omeprazole, a medicine used for indigestion or stomach ulcers
- rifampicin and rifabutin, medicines used to treat bacterial infection
- other medicines used to treat cancer

There are some medicines that may still be taken with Tarceva but may require close supervision by your doctor. These medicines include:

- warfarin, a medicine used to thin the blood

Your doctor will need to regularly monitor you with blood tests.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Tarceva.

In addition, grapefruit and grapefruit juice have an effect on how Tarceva works. Do not eat grapefruit or drink grapefruit juice while on treatment with Tarceva, except under the care of your doctor.

4. How to take Tarceva

How much to take

Take Tarceva exactly as your doctor has prescribed.

Your doctor will tell you how many Tarceva tablets to take each day.

For non-small-cell lung cancer, the usual dose is one 150 mg tablet each day.

For pancreatic cancer, given in combination with gemcitabine, the usual dose is one 100 mg tablet each day.

How to take it

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to take it

Take Tarceva tablets: at least 1 hour before you eat or at least 2 hours after you have eaten. Do not take Tarceva with food.

How long to take Tarceva

The duration of treatment with Tarceva varies, depending on the nature of your illness and your individual response to the treatment.

Continue taking Tarceva until your doctor tells you to stop.

If you forget to take Tarceva

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

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

If you take too much (overdose)

Contact your doctor or pharmacist immediately.

You may have increased side effects and your doctor may interrupt your treatment.

5. While you are using Tarceva

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Tarceva.

Tell your doctor if you become pregnant while taking Tarceva.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

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Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking Tarceva or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Tarceva to anyone else even if they have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Smoking may affect how well Tarceva works for you. If you smoke, you should stop smoking before starting treatment with Tarceva. Talk with your doctor about how to quit smoking. If you continue to smoke, you should talk to your doctor before taking Tarceva.

Things to be careful of

It is very unlikely that Tarceva will affect your ability to drive or use machines.

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

6. Side effects

Tell your doctor or pharmacist as soon as possible if you do not

feel well while you are taking Tarceva.

Tarceva helps people with non-small cell lung cancer and pancreatic 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 treatment if you get some of the side effects.

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

The most common side effects in patients who took Tarceva were generally mild to moderate rash and diarrhoea. You may also have other changes in your skin.

The rash from Tarceva therapy may appear on your upper body or face. Typically rash occurs within 8 days of starting treatment, but it may occur any time during treatment with Tarceva. The rash is not an allergic reaction. It may look like acne or dry skin. It is not acne.

Some suggestions to prevent rash are early use of alcohol-free moisturizer, avoidance of direct sunlight exposure and use a high-factor sunscreen whenever you are outdoors. However, talk to your doctor if a rash occurs.

Hair and nail changes have also been seen with Tarceva, but mostly are non-serious.

Typically, diarrhea may develop within 12 days of starting Tarceva. Diarrhoea is manageable with rehydration, Tarceva dose adjustment and medication as per your doctor's recommendation. Therefore, talk to your doctor if diarrhoea occurs.

Please see the Tarceva full prescribing information for complete safety information. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor immediately if you have these signs or symptoms:

- New or worsening skin rash
- Serious or ongoing diarrhoea, nausea, loss of appetite, or vomiting
- New or worsening shortness of breath or cough
- Eye irritation

Tell your doctor if you notice anything else that is making you feel unwell.

7. After using Tarceva

Storage

Keep your tablets in their container until it is time to take them.

If you take the tablets out of their container they may not keep well.

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Keep Tarceva in a cool dry place where the temperature stays below 30°C.

Keep Tarceva where young children cannot reach it.

Disposal

If your doctor tells you to stop taking Tarceva, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Malaysia Registration Number (MAL):

Tarceva film-coated tablet 25 mg [MAL20071623ARZ/MAL101000 27ARSZ]

Tarceva film-coated tablet 100 mg [MAL20071624ARZ/MAL101000 29ARSZ]

Tarceva film-coated tablet 150 mg [MAL20071625ARZ/MAL101000 28ARSZ]

8. Product Description

Availability

TARCEVA is available in three strengths, 25 mg, 100 mg and 150 mg.

Each tablet strength comes in packs of 30 tablets.

What TARCEVA looks like

- TARCEVA 25 mg tablets are white to yellowish, round tablets with "TARCEVA 25" and logo printed in brownish yellow on one side.
- TARCEVA 100 mg tablets are white to yellowish, round tablets with "TARCEVA 100" and logo printed in grey on one side.

- TARCEVA 150 mg tablets are white to yellowish, round tablets with "TARCEVA 150" and logo printed in brown on one side.

Ingredients

Active ingredient

- erlotinib

Inactive ingredients

- lactose monohydrate
- cellulose microcrystalline
- sodium starch glycolate type A
- sodium laurilsulfate
- magnesium stearate

The tablets have a film-coating which contains:

- hypromellose
- hydroxypropylcellulose
- macrogol
- titanium dioxide

The printing ink contains:

Tarceva 25 mg: shellac, iron oxide yellow (CI77492)

Tarceva 100 mg: shellac, iron oxide black (CI77499), titanium dioxide

Tarceva 150 mg: shellac, iron oxide red (CI77491)

9. Manufacturer

Made in Switzerland by F. Hoffmann-La Roche Ltd, Basel, Switzerland

Or

Made for F. Hoffmann-La Roche Ltd Basel, Switzerland, by Roche S.p.A Milan production site Segrate Italy.

Marketing Authorisation Holder

Roche (M) Sdn. Bhd.
Level 21, The Pinnacle,
Persiaran Lagoan, Bandar
Sunway,
47500 Subang Jaya, Selangor,
Malaysia.

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27 November 2017
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