

Consumer Medicine Information

TARCEVA[®]

Erlotinib hydrochloride

25 mg, 100 mg and 150 mg film-coated tablets

What is in this leaflet

This leaflet answers some common questions about TARCEVA tablets.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TARCEVA 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 TARCEVA is used for

TARCEVA contains the active ingredient erlotinib hydrochloride.

TARCEVA is used for the treatment of advanced or metastatic (spreading) non-small cell lung cancer (NSCLC) after initial chemotherapy. It can be given soon after initial chemotherapy or it can be given later on when the initial chemotherapy has not worked.

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

TARCEVA belongs to a group of medicines called anti-neoplastic (or anti-cancer) medicines, which are used to treat cancer.

TARCEVA prevents 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.

Your doctor may have prescribed TARCEVA for another purpose.

Ask your doctor if you have any questions about why TARCEVA has been prescribed for you.

TARCEVA is not addictive.

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

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**

Some 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, hives on the skin
2. **the package is torn or shows signs of tampering**
 3. **the expiry date 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 under 18 years of age.

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

Before you start to take TARCEVA

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.

If you are a woman who could become pregnant use adequate contraception (birth control) during treatment, and continue using contraception 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. TARCEVA is not generally recommended for use in pregnant women unless the benefits of treatment to the mother outweigh the risk to the unborn baby. Your doctor will discuss the risks and benefits of TARCEVA treatment with you.
2. **you are breast-feeding or plan to breast-feed**
It is not known whether TARCEVA 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 a smoker**
Your doctor may advise you to quit smoking as smoking can reduce the effectiveness of TARCEVA.
7. **you are allergic to any other medicines, foods, dyes or preservatives**
8. **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:

- ketoconazole (Nizoral[®]), a medicine used to treat fungal infections
- rifampicin (Rifadin[®], Rifinah[®]), a medicine used to treat infections
- ciprofloxacin (Cipflox[®], Ciproxen[®]), a medicine used to treat bacterial infections
- omeprazole (Losec[®], Omezol[®]), a medicine used to treat stomach reflux and stomach ulcers
- ranitidine (Zantac[®]), a medicine used to treat stomach reflux, and stomach ulcers
- antacids, a group of medicines used to treat stomach upset and indigestion

- corticosteroids, a group of medicines used to treat inflammation
- non-steroidal anti-inflammatory medicines (NSAIDs), a group of medicines commonly used as pain killers (examples include Nurofen[®] and Voltaren[®])
- statins, a groups of medicines used to lower cholesterol levels (examples include Lipitor[®] and Simvastatin[®])
- other medicines used to treat cancer

These medicines may be affected by TARCEVA, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

There are some medicines which may be taken with TARCEVA but may require close supervision by your doctor. These medicines include:

- warfarin (Coumadin[®], Marevan[®]), a medicine used to thin the blood. If you take warfarin 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.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take TARCEVA

Follow all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

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 TARCEVA tablet each day.

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

Your doctor may adjust your dose if necessary.

How to take it

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to take it

Take TARCEVA on an empty stomach.

Take TARCEVA at least one hour before food or two hours after food.

Food can interfere with the absorption and effectiveness of TARCEVA.

How long to take it

How long you will be treated with TARCEVA will depend on your cancer and how well you respond to the medicine.

Continue taking TARCEVA until your doctor tells you to stop.

If you forget to take it

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.

This may increase the chance of getting a side effect.

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to your nearest Accident and Emergency Centre, if you think you or anyone else may have taken too much TARCEVA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many tablets, you may get diarrhoea or a rash.

Keep telephone numbers for these places handy.

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

While you are taking 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.

If you are a smoker, try not to smoke while you are taking TARCEVA.

Smoking can interfere with how well TARCEVA will work and reduce the effectiveness of the medicine.

If you develop severe diarrhoea, tell your doctor immediately.

Your doctor may need to give you medicine to stop the diarrhoea, and may reduce your dose temporarily until the side effect settles.

If you develop severe abdominal pain associated with nausea and vomiting, or you develop blood in your stools, or if you are vomiting blood or material that looks like coffee grounds, tell your doctor immediately.

You may need urgent medical treatment.

If you suddenly develop a cough or worsening breathing difficulties with fever, tell your doctor immediately.

You may have interstitial lung disease, and may require urgent medical treatment.

If you develop eye-pain or blisters around the nose, mouth and eyes, tell your doctor immediately.

You may need urgent medical treatment.

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.

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 use TARCEVA to treat other complaints unless your doctor says to.

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

Things to be careful of

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

However, TARCEVA is not expected to affect your ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TARCEVA.

TARCEVA can help people with non-small cell lung cancer but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you. 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.

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

- tiredness
- loss of appetite
- itching
- dry skin
- acne
- folliculitis (infection of hair follicles)
- eye irritation, discharge with itching of the eyes and crusty eyelids
- nose bleeds
- unusual hair loss or thinning
- nail bed infection or swelling around the nails

These are the milder side effects of TARCEVA, and are usually short-lived.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- rash
- diarrhoea
- cough
- nausea or vomiting
- dehydration. Some signs of dehydration include dry skin, dark coloured urine, thirst, weakness or fatigue and loss of appetite
- weight loss

These side effects are usually short-lived, but may be persistent or get worse. Your doctor may recommend other medicines or may change the dose of TARCEVA if you experience these side effects.

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

- shortness of breath or, difficulty breathing
- infection, fever, chills
- pain, redness, swelling or sores in the mouth
- stomach pain
- numbness or weakness of the arms and legs
- depression

These may be serious side effects. Your doctor may recommend a change the dose of TARCEVA if you experience any of these side effects.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- **severe or persistent diarrhoea, nausea, loss of appetite or vomiting**
- **bleeding from the stomach or intestines**
Signs and symptoms may include severe stomach pain, vomiting blood or material that looks like coffee grounds, bleeding from your rectum, black sticky bowel motions, bloody diarrhoea.
- **sudden onset of new or progressively worsening breathing difficulties, associated with cough or fever**
These symptoms may indicate interstitial lung disease.
- **nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine**
- **blisters on the skin especially in the nose, mouth and eyes**
- **red or purple rash that spreads**
- **eye pain**

These may be very serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking 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.

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

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep TARCEVA where young 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 TARCEVA, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over. Do not throw out your medicine into the general household rubbish or flush it down the toilet.

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 marked with "TARCEVA 25" and a logo in brownish yellow on one side.
- TARCEVA 100 mg tablets are white to yellowish, round tablets marked with "TARCEVA 100" and a logo in grey on one side.
- TARCEVA 150 mg tablets are white to yellowish, round tablets marked with "TARCEVA 150" and a logo in brown on one side.

Ingredients

Active ingredient

erlotinib hydrochloride

Inactive ingredients

Lactose monohydrate, microcrystalline cellulose, sodium starch glycollate, sodium lauryl sulphate, magnesium stearate

The tablets have a film-coating which contains:

hydroxypropyl cellulose, titanium dioxide, polyethylene glycol, hydroxypropyl methylcellulose

The printing ink contains:

Shellac, iron oxide yellow, anhydrous ethanol, N-butyl alcohol, isopropyl alcohol, ethyl acetate. The 100 mg tablet also contains titanium dioxide and iron oxide black. The 150 mg tablet also contains iron oxide black and iron oxide red.

TARCEVA tablets are gluten free.

Distributor

TARCEVA is distributed by:

Roche Products (New Zealand) Limited
PO Box 12492 Penrose
Auckland 1642
NEW ZEALAND

Customer enquiries: 0800 656 464

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