

Tarceva®

Film-Coated Tablets

pronounced "tar-see-va"

contains the active ingredient erlotinib

Consumer Medicine Information

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 tablets 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.

Tarceva is used for the treatment of non-small cell lung cancer (NSCLC). It can be given before or after initial chemotherapy if your cancer has specific mutations in a protein called epidermal growth factor receptor (EGFR). It can also be given later on when 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) agents which are used to treat cancer.

Tarceva prevents the activity of the EGFR protein. 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 erlotinib 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 or hives on the skin

- 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.

Use in elderly

Reduction in dose is not required for elderly patients.

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:

- medicines used to treat heartburn, indigestion and ulcers, such as antacids, H₂ antagonists (e.g. ranitidine) and proton pump inhibitors (e.g. omeprazole)
- medicines used to treat HIV infection such as atazanavir, indinavir, ritonavir and saquinavir
- medicines used to treat epilepsy such as carbamazepine, phenobarbital (also known as phenobarbitone), phenytoin and midazolam
- medicines used to treat bacterial infections such as ciprofloxacin, clarithromycin,

erythromycin, rifampicin and rifabutin

- corticosteroids, a group of medicines used to treat inflammation
- medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole
- midazolam, a medicine used to cause drowsiness before an operation
- non-steroidal anti-inflammatory medicines (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- statins, a group of medicines used to lower cholesterol
- other medicines used to treat cancer

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

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 prevent blood clots

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.

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)

Immediately telephone your doctor or Poisons Information Centre (Australia telephone 13 11 26; New Zealand telephone 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think that 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.

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.

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

Smokers should stop smoking while taking Tarceva as blood levels of Tarceva may be reduced.

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.

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.

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

- rash
- diarrhoea
- your doctor may need to treat you with a medicine for this (e.g. loperamide)
- tiredness
- loss of appetite
- weight loss
- difficulty in breathing
- cough
- infection
- nausea or vomiting
- dehydration. Signs of dehydration include dry skin, dark coloured urine, thirst, weakness or fatigue and loss of appetite
- stomach pain or discomfort or belching after eating
- itching

- dry skin
- acne
- tear in the skin
- folliculitis (infection of the hair roots)
- unusual hair loss or thinning
- conjunctivitis, discharge with itching of the eyes and crusty eyelid or swollen runny eyes
- irritation or feeling of having something in the eye
- inflammation of the eye, including pain or redness, sensitivity to light or reduced vision
- nose bleeds
- nail bed infection or swelling around the nails
- headache
- fever
- rigors or shaking
- depression
- numbness or weakness of the arms and legs

These are the more common side effects of Tarceva that you are likely to notice. Your doctor will tell you more about them. Your doctor may also recommend that you change the dose of Tarceva that you are taking if you experience any of the above side effects.

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

- mouth irritation, sore mouth, mouth ulcers or cold sores
- persistent cough
- infection, fever, chills

These may be serious side-effects. Your doctor may interrupt your Tarceva treatment.

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

- shortness of breath or difficulty breathing with cough and/or fever.
- severe stomach pain or discomfort

- severe or persistent diarrhoea, nausea, vomiting or loss of appetite
- vomiting blood or material that looks like coffee grounds, bleeding from your back passage, black sticky bowel motions (stools), bloody diarrhoea
- tongue and/or facial swelling
- hives
- wheezing
- blisters on your skin, especially severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- painful red areas of skin, large blisters and/or peeling of layers of skin, accompanied by fever and chills, aching muscles and generally feeling unwell
- yellowing of the skin and eyes
- dark coloured urine

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 with "T 25" engraved on one side.
- Tarceva 100 mg tablets are white to yellowish, round tablets with "T 100" engraved on one side.
- Tarceva 150 mg tablets are white to yellowish, round tablets with "T 150" engraved on one side.

Ingredients

Active ingredient

- erlotinib

Inactive ingredients

- lactose
- microcrystalline cellulose
- sodium starch glycollate
- sodium lauryl sulfate
- magnesium stearate

The tablets have a film-coating which contains:

- hypromellose
- hydroxypropylcellulose
- macrogol
- titanium dioxide

Tarceva tablets are gluten free.

Distributor

In Australia Tarceva is distributed by:

Roche Products Pty Limited
 ABN 70 000 132 865
 Level 8, 30-34 Hickson Road
 Sydney NSW 2000
 Medical enquiries: 1800 233 950

Australian Registration Numbers

- 25 mg - AUST R 114714
- 100 mg - AUST R 114717
- 150 mg - AUST R 114721

In New Zealand Tarceva is distributed by:

Roche Products (New Zealand) Limited
 PO Box 109113 Newmarket
 Auckland 1149
 NEW ZEALAND

Medical enquiries: 0800 656 464

Please check with your pharmacist
for the latest Consumer Medicine
Information.

This leaflet was prepared on 01
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