

# TARCEVA Film-Coated Tablets

pronounced "tar-see-va"

*contains the active ingredient erlotinib*

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## Consumer Medicine Information

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### What is in this leaflet

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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.

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### What TARCEVA is used for

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TARCEVA contains the active ingredient erlotinib.

TARCEVA is used for the treatment of non-small cell lung cancer 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 agents 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.

TARCEVA is prescribed to patients who have non-small cell lung cancer at an advanced stage and chemotherapy has not helped to stop your disease, or you have advanced stage pancreatic cancer.

Your doctor may have prescribed TARCEVA for another purpose.

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

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

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### Before you take TARCEVA

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#### *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.

#### ***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, immediately inform your doctor.

- 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 are allergic to any other medicines, foods, dyes or preservatives

### 5. you cannot tolerate some sugars.

**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 from a pharmacy, supermarket or healthfood shop.**

Some medicines may interfere with TARCEVA. These medicines include:

- \* atazanavir
- \* carbamazepine
- \* clarithromycin
- \* erythromycin
- \* indinavir
- \* itraconazole
- \* ketoconazole
- \* nelfinavir
- \* phenobarbital
- \* phenytoin
- \* rifabutin
- \* rifampicin
- \* ritonavir
- \* saquinavir
- \* voriconazole

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.

A herb called St John's Wort may interfere with TARCEVA.

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

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## **How to take TARCEVA**

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### ***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 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.**

### ***In case of an overdose***

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) 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.**

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## **While you are taking TARCEVA**

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### ***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.**

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## **Side effects**

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**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 an anti-diarrhoeal (e.g. loperamide)

- \* tiredness
- \* loss of appetite
- \* difficulty in breathing
- \* cough
- \* infection
- \* nausea
- \* vomiting
- \* mouth irritation
- \* stomach pain
- \* itching
- \* dry skin
- \* hair loss
- \* eye irritation
- \* nose bleeds

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.

TARCEVA may also cause the following:

- \* bleeding from the stomach or intestines
- \* abnormal liver function test results

**Tell your doctor if you have persistent diarrhoea, nausea, loss of appetite or vomiting because your doctor may need to interrupt your TARCEVA treatment.**

**Tell your doctor immediately if you develop symptoms of interstitial lung disease.**

Signs and symptoms include sudden difficulty breathing associated with cough or fever.

This is an uncommon serious side effect of a rare form of lung irritation. It can be linked to the natural progression of your medical condition and can have a fatal outcome in some cases.

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.

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## **After taking TARCEVA**

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### ***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 degrees 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.**

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## **Product description**

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### ***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
- \* microcrystalline cellulose
- \* sodium starch glycollate
- \* sodium lauryl sulfate
- \* magnesium stearate

The tablets have a film-coating which contains:

- \* hypromellose
- \* hydroxypropylcellulose
- \* macrogol
- \* titanium dioxide

The printing ink contains:

- \* iron oxide yellow (CI77492)
- \* iron oxide black (CI77499)
- \* iron oxide red (CI77491)

TARCEVA tablets are gluten free.

Customer enquiries: 1 800 233 950

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

For further information please go to [www.tarceva.com.au](http://www.tarceva.com.au)

The password is the first four digits of the TARCEVA Australian Registration Number.

#### Australian Registration Numbers

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

This leaflet was prepared on 13 September 2006.

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## **Distributor**

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TARCEVA is distributed by:

Roche Products Pty Limited  
ABN 70 000 132 865  
4-10 Inman Road  
Dee Why NSW 2099