

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking IRESSA?

IRESSA contains the active ingredient gefitinib. IRESSA is used to treat non-small cell lung cancer, which is one type of lung cancer.

For more information, see Section [1. Why am I taking IRESSA?](#) in the full CMI.

2. What should I know before I taking IRESSA?

Do not take it if you have ever had an allergic reaction to IRESSA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take IRESSA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IRESSA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take IRESSA?

- The usual adult dose is one 250 mg tablet taken each day.
- Swallow your IRESSA tablet whole with a glass of water. Do not chew or crush the tablets.

More instructions can be found in Section [4. How do I take IRESSA?](#) in the full CMI.

5. What should I know while taking IRESSA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking IRESSA. • Be sure to keep all your appointments with your doctor so your progress can be checked. • If you become pregnant while taking IRESSA, tell your doctor right away.
Things you should not do	• Do not stop taking this medicine suddenly. • Do not stop taking IRESSA without checking with your doctor. • Do not give IRESSA to anyone else, even if they have the same condition as you. • Do not take IRESSA to treat any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how IRESSA affects you.
Looking after your medicine	• Keep it in a cool dry place where the temperature stays below 30°C. • Keep your IRESSA tablets in the blister foil until it is time to take them.

For more information, see Section [5. What should I know while taking IRESSA?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some can be minor and temporary. However, some side effects may be serious and possibly fatal, therefore will need immediate medical attention. See Section 6 in the full CMI ([6. Are there any side effects?](#)) and, if you need to, ask your doctor if you have any further questions about side effects. Tell your doctor if you experience any side effects, including those not listed in this leaflet.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking IRESSA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking IRESSA.**

Where to find information in this leaflet:

1. [Why am I taking IRESSA?](#)
2. [What should I know before I take IRESSA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take IRESSA?](#)
5. [What should I know while taking IRESSA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking IRESSA?

IRESSA contains the active ingredient gefitinib. IRESSA belongs to a group of medicines called antineoplastics. These medicines work by stopping cancer cells from growing and multiplying.

IRESSA is used to treat non-small cell lung cancer, which is one type of lung cancer.

Your doctor will have explained why you are being treated with IRESSA and told you what dose to take.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

This medicine is available only with a doctor's prescription. IRESSA is not addictive.

2. What should I know before I take IRESSA?

Warnings

Do not take IRESSA if:

- you are allergic to gefitinib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.

Symptoms of an allergic reaction to IRESSA may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin
- dizziness or light-headedness
- back pain

Check with your doctor if you:

- have any other medical conditions:
 - o eye problems. You may need further examination.
 - o lung problems
 - o liver problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take IRESSA if you are pregnant.

It is not known if it is safe for you to take IRESSA while you are pregnant. It may affect your baby if you take it at any time during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breastfeed while taking IRESSA.

IRESSA passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Children

Do not give IRESSA to children.

There is no experience of its use in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any other medicines, including:

- itraconazole & ketoconazole (medicines used to treat fungal infections)
- metoprolol (beta-blocker)
- rifampicin (antibiotic)
- warfarin (blood thinner)
- phenytoin, carbamazepine, barbiturates, St John's Wort
- vinorelbine (cancer drug)
- medicines that alter the acidity of the stomach e.g. antacids, H2 antagonists and proton pump inhibitors

These medicines may interfere with IRESSA and affect how it works.

You may need different amounts of your medicine, or you may need to take/use/have different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking IRESSA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IRESSA.

4. How do I take IRESSA?

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

- The usual adult dose is one 250 mg tablet taken each day.

Swallow your IRESSA tablet whole with a glass of water. Do not chew or crush the tablets.

For patients with swallowing difficulties the tablet can be dissolved in drinking water (non-carbonated). No other liquids should be used. Follow these instructions carefully:

1. Drop the tablet into half a glass of drinking water (non-carbonated). DO NOT CRUSH THE TABLET.
2. Stir the water until the tablet dissolves and the water becomes a cloudy pale orange solution (approximately 10 minutes).
3. Drink the liquid immediately.
4. Rinse the empty glass with half a glass of drinking water and drink the water.

This cloudy pale orange solution can also be given to patients via a nasogastric tube.

- Follow the instructions provided and take IRESSA until your doctor tells you to stop.

When to take IRESSA

- **IRESSA should be taken regularly at about the same time each day.** Taking IRESSA at the same time each day will help you remember to take it.
- It does not matter if you take IRESSA with or without food.
- **Continue taking IRESSA for as long as your doctor tells you.**

When to take IRESSA

- Continue taking IRESSA for as long as your doctor tells you.

If you forget to take IRESSA

IRESSA should be taken regularly at the same time each day. **If you miss your dose at the usual time, take it as soon as you remember, as long as it is 12 hours before the next dose is due.**

If it is less than 12 hours to the next dose do not take the dose you have missed.

Do not take a double dose to make up for the dose you missed.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much IRESSA

If you think that you have taken too much IRESSA you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an IRESSA overdose include the side effects listed below Section [6. Are there any side effects](#), but are usually of a more severe nature.

5. What should I know while taking IRESSA?

Things you should do

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

Your doctor may want to do some tests from time to time to check your progress and investigate any unwanted side effects.

Call your doctor straight away if you:

- become pregnant
- experience any of the serious side effects listed in Section [6. Are there any side effects](#).

Remind any doctor, dentist or pharmacist you visit that you are taking IRESSA.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking IRESSA.

If you go into hospital, please let the medical staff know you are taking IRESSA.

Things you should not do

- Do not stop taking this medicine suddenly.
- Do not stop taking IRESSA without checking with your doctor

- Do not give IRESSA to anyone else, even if they have the same condition as you.
- Do not take IRESSA if the packaging is torn or shows signs of tampering.
- Do not take IRESSA to treat any other complaints unless your doctor tells you to.

Driving or taking machines

Be careful before you drive or use any machines or tools until you know how IRESSA affects you.

Some patients may feel weak.

Looking after your medicine

- **Keep your IRESSA tablets in the blister foil until it is time to take them.** If you take IRESSA out of the blister foil, it will not keep well.
- **Keep it in a cool dry place where the temperature stays below 30°C.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• skin reactions such as acne-like rash, sometimes itchy with dry and/or cracked skin • nausea (feeling sick) • diarrhoea • vomiting • loss of appetite or weight changes • red or sore mouth • dry mouth	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• problems with your nails • hair loss • unusual tiredness or weakness • eye problems, including red and itchy eye, red and sore eyelid, dry eyes • increased bleeding (e.g. nose bleeds, blood in your urine) • fever • burning sensations during urination and frequent, urgent need to urinate • skin reaction on the palms of the hands and soles of the feet including tingling, numbness, pain, swelling or reddening (known as palmar-plantar erythrodysesthesia syndrome or hand and foot syndrome)	

Serious side effects

Serious side effects	What to do
• severe skin reactions affecting large portions of your body including redness, pain, ulcers, blisters, skin sloughing or involvement of lips and mucous membranes (toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme) • Dehydration following persistent or severe diarrhoea, vomiting, nausea (feeling sick) or loss of appetite • serious breathlessness, or sudden worsening breathlessness, possibly with a cough or fever. Some patients taking IRESSA get an inflammation of the lungs called interstitial lung disease. This side effect is common and some of the patients have died from this. • unexpected bleeding, if you are also taking warfarin • new eye problem, such as pain, redness, watery eyes, light sensitivity or changes in your vision. Some patients have suffered from ulcer of the eye (cornea), sometimes with ingrowing eyelashes • allergic reactions, including swelling of the face, lips, tongue or other parts of the body	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
including hands, feet or ankles and hives - inflammation of the liver. Symptoms may include a general feeling of unwell with or without jaundice (yellowing of the skin or eyes). This side effect is uncommon; however, some patients have died from this. - inflammation of the pancreas, with symptoms such as very severe pain in the upper part of the stomach area and severe nausea (feeling sick) and vomiting - gastrointestinal perforation. Symptoms may include abdominal pain, nausea, vomiting and fever - Inflammation of the blood vessels in the skin. This may give the appearance of bruising or patches of non-blanching rash on the skin	

IRESSA may be associated with changes in your blood, urine or liver. Your doctor may want to perform tests from time to time to check on your progress and detect any unwanted side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What IRESSA contains

Active ingredient (main ingredient)	gefitinib
Other ingredients (inactive ingredients)	- lactose monohydrate - microcrystalline cellulose - croscarmellose sodium - povidone - sodium lauryl sulphate

	- magnesium stearate - hypromellose - macrogol 300 - titanium dioxide - iron oxide yellow - iron oxide red
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Do not take this medicine if you are allergic to any of these ingredients.

What IRESSA looks like

IRESSA 250 mg tablets are brown, round, film-coated tablets. One side of the tablet is marked "IRESSA 250".

IRESSA tablets are packed in blister foils of 30 tablets. (AUST R 90010)

Who distributes IRESSA

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

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