

# IRESSA® 250MG FILM-COATED TABLET

Gefitinib (250mg)

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## What Iressa is used for

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

## How Iressa works

Iressa contains the active substance gefitinib which blocks a protein called 'epidermal growth factor receptor' (EGFR). This protein is involved in the growth and spread of cancer cells.

## Before you use Iressa

### - When you must not use it

Do not take Iressa if you are allergic to gefitinib or any of the other ingredients of Iressa, listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.

Iressa is not recommended for use in children or adolescents.

### - Before you start to use it

Before taking Iressa:

- Tell your doctor if you have or have had any other lung diseases, other than your lung cancer. Some of them may worsen during treatment with Iressa.
- Tell your doctor if you are pregnant or trying to become pregnant. You should avoid becoming pregnant during treatment with Iressa.

- Tell your doctor if you are breast-feeding. For the safety of your baby, you should discontinue breast-feeding during treatment with Iressa.

### - Taking other medicines

**Please inform your doctor** if you are taking or have taken any medicines (including medicines taken some time ago), even those not prescribed. Your doctor especially needs to know:

- if you take any of the following medicines: phenytoin, carbamazepine, rifampicin, barbiturates, St John's Wort or itraconazole, or any medicines that reduce the acidity on your stomach, such as ranitidine. These medicines may affect the way Iressa works.
- if you take warfarin (to prevent blood-clots), as Iressa may affect it. Your doctor may need to check your blood more often.

## How to use Iressa

### - How much to use & when to use it

Take one 250 mg tablet, once a day, every day about the same time. You can take Iressa with or without food.

For individuals who are only able to swallow liquids, the tablet may be used as a dispersion in water. The tablet should be dropped into half a glass of drinking water (non-carbonated), without crushing, and the glass stirred until the tablet has dispersed (approximately 15 minutes) and the contents subsequently drunk immediately. The glass should be rinsed with a further half glass of water and the contents drunk.

The liquid can also be used via a nasogastric tube.

### - How long to use it

Take Iressa as directed by your Healthcare provider.

### - If you forget to use it

If you forget to take a dose, take the last missed dose as soon as you remember, as long as it is at least 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 (two doses at the same time) to make up for a forgotten dose.

### - If you use too much (overdose)

If you take more than the recommended number of tablets, contact a doctor or pharmacist immediately. An increase of frequency and severity of some adverse reactions was observed, mainly diarrhea and skin rash.

## While you are using it

### - Things you must do

It is important to keep taking Iressa as your doctor has told you to. The instructions on the label should remind you of what the doctor has said.

### - Things you must not do

Do not stop taking your dose without talking to your Healthcare provider.

### - Things to be careful of

#### Driving and using machines

During treatment with Iressa, lack of energy and strength has been reported and those people who experience this symptom should observe caution when driving or using machines.

## Side effects

Like all medicines, Iressa can have side effects. These are usually mild to moderate in intensity. Do not be alarmed by the list of side

effects. You may not have any of them.

Contact your doctor without delay if any of the following happens to you, as you may need further examinations or treatment:

- Serious breathlessness, or sudden worsening breathlessness, possibly with a cough or fever. Some individuals taking Iressa get an inflammation of the lungs called interstitial lung disease. This side effect is common (about 1 of every 100 people are likely to have it), and some people have died from this.
- Unexpected bleeding, if you are also taking warfarin.
- Some people have suffered from dehydration (1 to 10 of every 100 people) following persistent or severe diarrhoea, vomiting, nausea (feeling sick) or loss of appetite.
- New or worsening eye problems, such as pain, redness, watery eyes, light sensitivity or changes in your vision. Some people have suffered from ulcer on the surface of the eye (cornea), sometimes with ingrowing eyelashes; this side effect is uncommon (less than 1 in every 100 people).
- 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). This type of skin reaction is rare (less than 1 in every 1,000 people is likely to have them).

Tell your doctor if any of the following side effects bothers you:

Side effects that are very common (more than 10 of every 100 people are likely to have them):

- Diarrhoea
- Nausea (feeling sick)

- Skin reactions such as acne-like rash, sometimes itchy with dry and/or cracked skin
- Vomiting
- Loss of appetite
- Weakness
- Red and sore mouth

Side effects that are common (1 to 10 of every 100 people are likely to have them):

- Dry mouth
- Nail problems
- Loss of hair
- Dry eye
- Red and itchy eye
- Red and sore eyelid
- Nose bleed and blood in your urine
- Fever
- Protein in your urine (shown in a urine test)
- Cystitis (burning sensations during urination and frequent, urgent need to urinate)
- Allergic reactions, including swelling of lips, face, tongue or throat and hives or nettle-rash

Side effects that are uncommon (less than 1 in every 100 people is likely to have them)

- 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.
- Inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without possible jaundice (yellowing of the skin and eyes). This side effect is uncommon; however, some people have died from this.
- Gastrointestinal perforation
- 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).

Side effects that are rare (less than 1 in every 1,000 people is likely to have them)

- Inflammation of the blood vessels in the skin. This may give the appearance of bruising or patches of non-blanching rash on the skin.
- Haemorrhagic cystitis

The following side effects can also occur with Iressa, and they are seen when a blood test is taken:

- Changes of the levels of liver enzymes and bilirubin. If these levels become very high, your doctor may need to stop the treatment.
  - Changes to the level of one liver enzyme known as alanine aminotransferase (ALT) is very common (more than 10 of every 100 people)
  - Changes to the level of bilirubin and the other liver enzyme known as aspartate aminotransferase (AST) are common (1 to 10 of every 100 people)
- Changes to the level of creatinine in your blood, which show how well your kidneys are working. This side effect is common (1 to 10 of every 100 people).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

#### **Storage & Disposal of Iressa** **- Storage**

- Keep out of the reach and sight of children.
- Do not store above 30°C.

- Keep Iressa in the original container in order to protect from moisture.
- Do not use Iressa after the expiry date on the blister pack.

**- Disposal**

- Remember to return any unused Iressa to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Registration Holder**

AstraZeneca Sdn. Bhd.  
Level 11 & 12, The Bousteador,  
10, Jalan PJU 7/6,  
Mutiarra Damansara,  
47800 Petaling Jaya,  
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**Date of revision**

27/09/2024  
VV-RIM-01423687  
(based on PI: VV-RIM-01423686)

**Serial number**

NPRA(R2/1)210119/605

**Product Description**

**- What it looks like**

Brown, round, biconvex, film-coated tablet impressed with "IRESSA 250" on one side and plain on the other.

Each tablet contains 250 mg gefitinib.

Iressa tablets come in blister packs containing 30 tablets.

**- Ingredients**

- Active ingredient: gefitinib.

- Inactive ingredients: Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Povidone (K29/32), Sodium Lauryl Sulphate, Magnesium Stearate, Hypromellose, Macrogol, Red Iron Oxide (CI 77491), Yellow Iron Oxide (CI 77492), Titanium Dioxide, Anhydrous Ethanol, Purified Water.

**- MAL number:**

MAL19086008ACRZ

**Manufacturer**

Kagamiishi Plant, Nipro Pharma Corporation  
428 Okanouchi  
Kagamiishi-machi  
Iwase-gun  
Fukushima  
Japan