

# Iressa<sup>®</sup>

## gefitinib 250 mg tablets

### CONSUMER MEDICINE INFORMATION

#### What is in this leaflet

This leaflet answers some of the common questions people ask about **Iressa**. It does not contain all the information that is known about **Iressa**.

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

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Iressa** 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 Iressa is used for

**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.

#### How Iressa works

**Iressa** is a selective inhibitor of a growth factor that is found in non-small cell lung cancer. By blocking the action of the growth factor **Iressa** may slow or stop the growth of non-small cell lung cancer.

#### Before you use Iressa

##### ***When you must not use it***

##### **Do not use Iressa if:**

- You are allergic to gefitinib or any of the other ingredients of Iressa;

**Do not use 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.

**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.

**Do not give Iressa to children.** There is no experience of its use in children.

**Do not take Iressa after the use by (expiry) date printed on the pack.**

**Do not use Iressa if the packaging is torn or shows signs of tampering.**

**Do not use it to treat any other complaints unless your doctor tells you to.**

**Do not give this medicine to anyone else even if their symptoms seem similar to yours.**

##### ***Before you start to use Iressa***

Before taking **Iressa**, tell your doctor if:

1. you have any eye problems. You may need further examination.
2. you have any other lung problems such as pneumonia
3. you have any liver problems

##### ***Taking other medicines***

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

- phenytoin
- carbamazepine
- rifampicin
- barbiturates
- St John's Wort
- Itraconazole, ketoconazole
- metoprolol
- vinorelbine
- warfarin
- medicines that alter the acidity of the stomach eg. antacids, H2 antagonists and proton pump inhibitors
- medicines that you buy at your pharmacy, supermarket or health food shop.

These medicines may be affected by **Iressa**, or may affect how well 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**.

If you have not told your doctor about any of these things, tell them before you start taking any **Iressa**.

### Using Iressa

#### ***Taking your medicine***

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

#### **The usual dose is one 250 mg tablet each day.**

It is best to take your tablet at the same time each day, e.g. in the morning, but it does not matter whether you take it with or without food. Swallow the tablet whole with a glass of water. Do not chew or crush the tablet.

For patients with swallowing difficulties the tablet can also be dispersed in half a glass of drinking water (non-carbonated). No other liquids should be used. Drop the tablet in the water without crushing it, stir until the tablet is dispersed (approximately 10 minutes) and drink the liquid immediately. Rinse the glass with half a glass of water and drink. This cloudy, pale orange solution can also be given to patients via a nasogastric tube.

#### ***How long to take Iressa***

Continue taking **Iressa** for as long as your doctor tells you.

#### ***If you forget to take Iressa***

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 to make up for the dose that you missed.**

#### ***Overdose***

**Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre (Ph: 03 474 7000) or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too much Iressa. Even if there are no signs of discomfort or poisoning.**

### While you are using Iressa

#### ***Things you must 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.

If you become pregnant tell your doctor immediately.

Tell any other doctors, dentists and pharmacists who are treating you 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 must not do:**

**Do not stop taking Iressa without checking with your doctor.**

**Things to be careful of:**

Be careful driving or operating machinery until you know how **Iressa** affects you. Some patients may feel weak.

<b>Side effects</b>
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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Iressa.**

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 as soon as possible if you notice any of the following and they worry you**

- skin reactions such as acne-like rash, sometimes itchy with dry skin
- nausea
- vomiting
- loss of appetite or weight changes
- red or sore mouth
- dry mouth
- problems with your nails
- hair loss
- unusual tiredness or weakness
- eye problems, including red and itchy eye, red and sore eyelid, dry eyes, watery eyes, light sensitivity or changes in your vision
- increased bleeding
- (eg 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)

**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.

These are possible side effects of **Iressa**.

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

- severe skin reactions with lesions, ulcers or blisters
- diarrhoea
- severe eye problems including an eye ulcer, sometimes with ingrowing eyelashes
- unexplained breathing problems
- these side effects may be serious

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen**

- rash, itching or hives on the skin,
- swelling of the face, lips, tongue or other parts of the body including hands, feet or ankles
- breathlessness/shortness of breath, wheezing or trouble breathing

- liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin or eyes)

Some patients taking **Iressa** get an inflammation of the lungs called interstitial lung disease. This side effect is common.

These are all serious side effects. You may need urgent medical attention or hospitalisation.

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

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.** Some people may get other effects while taking **Iressa**.

**Important:** This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Iressa**.

### After using Iressa

#### **Storage**

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

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

**Do not leave it in the car on hot days.**

#### **Disposal**

Return any unused medicine to your pharmacist (chemist).

### Product description

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

Each tablet contains 250 mg of gefitinib as the active ingredient.

Other ingredients:

- Lactose monohydrate
- Microcrystalline cellulose
- Croscarmellose sodium
- Povidone
- Sodium lauryl sulphate
- Magnesium stearate
- Hypromellose
- Macrogol 300
- Titanium dioxide
- Yellow iron oxide
- Red iron oxide.

**Iressa** comes in a blister pack containing 30 tablets.

### Marketed by:

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