

**Cipla Gefitinib**  
**250 mg film-coated tablets**  
*Gefitinib*

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**Consumer Medicine Information**

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**What is in this leaflet**

This leaflet answers some of the common questions people ask about Cipla Gefitinib. 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 will have weighed the risks of you taking Cipla Gefitinib 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 Cipla Gefitinib is for**

Cipla Gefitinib belongs to a group of medicines called antineoplastics. These medicines work by stopping cancer cells from growing and multiplying.

Cipla Gefitinib 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 Cipla Gefitinib 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.

Cipla Gefitinib is not addictive.

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**Before you use Cipla Gefitinib**

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**When you must not use it**

**You must tell your doctor if you have allergies to:**

- gefitinib, the active ingredient in Cipla Gefitinib
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Cipla Gefitinib 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 lightheadedness
- back pain

**Do not use Cipla Gefitinib if you are pregnant.**

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

**Do not breastfeed while taking Cipla Gefitinib.**

Gefitinib passes into breast milk and therefore there is a possibility that the breastfed baby may be affected.

**Do not give Cipla Gefitinib to children.**

There is no experience of its use in children.

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

**Do not take Cipla Gefitinib 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.**

**Before you start to use it**

**You must tell your doctor if:**

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

**Cipla Gefitinib contains lactose monohydrate**

Do not take Cipla Gefitinib if you have the rare hereditary problems of glucose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

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**Taking other medicines**

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

- itraconazole & ketoconazole (medicines used to treat fungal infections)
- metoprolol (betablocker)
- rifampicin (antibiotic)
- warfarin (blood thinner)
- phenytoin, carbamazepine, barbiturates, St John's Wort
- vinorelbine (cancer drug)
- medicines that alter the acidity of the stomach eg. antacids, H2 antagonists and proton pump inhibitors
- medicines that you buy at the chemist, supermarket or health food shop

These medicines may be affected by Cipla Gefitinib, 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 Cipla Gefitinib.

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

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**Taking Cipla Gefitinib**

**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.**

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**How much to take**

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

**Swallow your Cipla Gefitinib 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 (noncarbonated). 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 15 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.

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**When to take it**

**Take Cipla Gefitinib at about the same time each day.**

Taking Cipla Gefitinib at the same time each day will help you remember to take it.

It does not matter if you take Cipla Gefitinib with or without food.

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**How long to take it**

**Continue taking Cipla Gefitinib for as long as your doctor tells you.**

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**If you forget to take it**

**If you miss a dose 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 that 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.**

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**Overdose**

**Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Cipla Gefitinib. Do this even if there are no signs of discomfort or poisoning.**

**Symptoms of an Cipla Gefitinib overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.**

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**While you are using it**

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**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 Cipla Gefitinib.**

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

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

### **Things you must not do**

**Do not give Cipla Gefitinib to anyone else, even if they have the same condition as you.**

**Do not take Cipla Gefitinib to treat any other complaints unless your doctor tells you to.**

**Do not stop taking Cipla Gefitinib without checking with your doctor.**

### **Things to be careful of**

**Be careful driving or operating machinery until you know how Cipla Gefitinib affects you.**

Some patients may feel weak.

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## Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Cipla Gefitinib.**

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
- increased bleeding (eg nose bleeds, blood in your urine)
- fever
- burning sensations during urination and frequent, urgent need to urinate, blood in the urine

Cipla Gefitinib 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 Cipla Gefitinib.

**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 Cipla Gefitinib 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 Cipla Gefitinib.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly at <http://www.tga.gov.au/reporting-problems>. By reporting side effects you can help provide more information on the safety of this medicine.

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## After using it

### **Storage**

**Keep your Cipla Gefitinib tablets in the blister foil until it is time to take them.**

If you take Cipla Gefitinib out of the blister foil, it will not keep well.

**Keep it 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.**

**Do not leave it on a window sill or in the car on hot days.**

Heat and dampness can destroy some medicines.

**Keep your medicine where 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**

**Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.**

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## Product description

### **What Cipla Gefitinib looks like**

Cipla Gefitinib tablets are round, biconvex, brown film coated tablets debossed with 'C' on one side and plain on the other side. Diameter: 11.10 mm ± 0.20 mm.

Cipla Gefitinib tablets are packed in blister foils of 30 tablets.

### **Ingredients**

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

### **Other ingredients**

#### *Tablet core*

- Lactose monohydrate,

- Microcrystalline cellulose,
- Croscarmellose sodium,
- Povidone,
- Sodium lauryl sulphate,
- Magnesium stearate.

#### *Tablet coat*

- Polyvinyl alcohol-part hydrolysed,
- Macrogol,
- Purified talc,
- Titanium dioxide,
- Yellow iron oxide,
- Red iron oxide.

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## Sponsor

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