

# Cipla Gefitinib

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I using Cipla Gefitinib?

Cipla Gefitinib contains the active ingredient gefitinib. Cipla Gefitinib 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 using Cipla Gefitinib?](#) in the full CMI.

### 2. What should I know before I use Cipla Gefitinib?

Do not use if you have ever had an allergic reaction to Cipla Gefitinib 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 use Cipla Gefitinib?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Cipla Gefitinib 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 use Cipla Gefitinib?

- 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.

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

### 5. What should I know while using Cipla Gefitinib?

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Cipla Gefitinib.</li><li>• Be sure to keep all your appointments with your doctor so your progress can be checked.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not give Cipla Gefitinib to anyone else, even if they have the same condition as you.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Cipla Gefitinib affects you.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Keep it in a cool dry place where the temperature stays below 30°C.</li><li>• Keep your Cipla Gefitinib tablets in the blister foil until it is time to take them.</li></ul>

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

### 6. Are there any side effects?

Common side effects- skin reactions such as acne-like rash, sometimes itchy with dry skin, palmar-plantar erythrodysaesthesia syndrome or hand and foot syndrome, nausea, unusual tiredness or weakness. Serious side-effects- severe skin reactions with lesions, ulcers or blisters, severe eye problems including an eye ulcer, sometimes with ingrowing eyelashes, diarrhoea, unexplained breathing problems, liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin or eyes).

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.

# Cipla Gefitinib

Active ingredient(s): *gefitinib*

## Consumer Medicine Information (CMI)

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

### Where to find information in this leaflet:

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

### 1. Why am I using Cipla Gefitinib?

Cipla Gefitinib contains the active ingredient gefitinib. Cipla Gefitinib is 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.

### 2. What should I know before I use Cipla Gefitinib?

#### Warnings

##### Do not use Cipla Gefitinib 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 use this medicine.

##### Check with your doctor if you:

- Have shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- Have swelling of the face, lips, tongue or other parts of the body
- Have rash, itching, hives or flushed, red skin
- Have dizziness or lightheadedness
- Have back pain
- Have any eye problems. You may need further examination.
- Have any lung problems such as pneumonia
- Have any liver problems.

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.

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

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.

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

### Do not give Cipla Gefitinib 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 eg. antacids, H2 antagonists and proton pump inhibitors

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.

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

### 4. How do I use Cipla Gefitinib?

#### 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.

### **When to take Cipla Gefitinib**

- Cipla Gefitinib should be used at the same time each day.

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

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

### **If you forget to use Cipla Gefitinib**

Cipla Gefitinib should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

- 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.

### **If you use too much Cipla Gefitinib**

If you think that you have used too much Cipla Gefitinib, 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.**

## **5. What should I know while using Cipla Gefitinib?**

### **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:**

- are pregnant
- are about to be started on any new medicine

**Remind any doctor, dentist or pharmacist you visit that you are using Cipla Gefitinib.**

### **Things you should not do**

- Do not stop using this medicine suddenly.
- 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.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Cipla Gefitinib affects you.**

Cipla Gefitinib may cause dizziness in some people

### **Looking after your medicine**

- Keep it in a cool dry place where the temperature stays below 30°C.
- 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.
- Heat and dampness can destroy some medicines.
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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.

**Keep it where young children cannot reach it.**

### **Getting rid of any unwanted medicine**

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

Do not use 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
<ul style="list-style-type: none"><li>skin reactions such as acne-like rash, sometimes itchy with dry skin</li><li>nausea</li><li>vomiting</li><li>loss of appetite or weight changes</li><li>red or sore mouth</li><li>dry mouth</li><li>problems with your nails</li><li>hair loss</li><li>unusual tiredness or weakness</li><li>eye problems, including red and itchy eye, red and sore eyelid, dry eyes</li><li>increased bleeding (eg nose bleeds, blood in your urine)</li><li>fever</li><li>burning sensations during urination and frequent, urgent need to urinate, blood in the urine</li><li>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)</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>severe skin reactions with lesions, ulcers or blisters</li><li>diarrhoea</li><li>severe eye problems including an eye ulcer, sometimes with ingrowing eyelashes</li><li>unexplained breathing problems</li><li>rash, itching or hives on the skin,</li><li>swelling of the face, lips, tongue or other parts of the body including hands, feet or ankles</li><li>breathlessness/shortness of breath, wheezing or trouble breathing</li><li>liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin or eyes)</li></ul>	<p><b>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.</b></p>

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.

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

**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](http://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 Cipla Gefitinib contains

Active ingredient	Gefitinib
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"><li>Lactose monohydrate,</li><li>Microcrystalline cellulose,</li><li>Croscarmellose sodium,</li><li>Povidone,</li><li>Sodium lauryl sulphate,</li><li>Magnesium stearate</li><li>Polyvinyl alcohol-part hydrolysed,</li><li>Macrogol,</li><li>Purified talc,</li><li>Titanium dioxide,</li><li>Yellow iron oxide,</li><li>Red iron oxide.</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Cipla Gefitinib looks like

Cipla Gefitinib is 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. (Aust R 318433).

**Who distributes Cipla Gefitinib**

Cipla Australia Pty Ltd  
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South Melbourne Vic 3205  
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