

# ERLOTINIB SANDOZ®

## 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 Erlotinib Sandoz?

Erlotinib Sandoz contains the active ingredient erlotinib. Erlotinib Sandoz is used for the treatment of non-small cell lung cancer (NSCLC) or in combination with gemcitabine for the treatment of pancreatic cancer.

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

### 2. What should I know before I use Erlotinib Sandoz?

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

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

Some medicines may interfere with Erlotinib Sandoz 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 Erlotinib Sandoz?

Your doctor will tell you how many Erlotinib Sandoz tablets to take each day.

- For non-small-cell- lung cancer, the usual dose is one 150 mg tablet each day.
- For pancreatic cancer, given in combination with gemcitabine, the usual dose is one 100 mg tablet each day.

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

### 5. What should I know while using Erlotinib Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Erlotinib Sandoz.</li><li>• Tell your doctor if you become pregnant while taking Erlotinib Sandoz.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking Erlotinib Sandoz or change the dose without first checking with your doctor.</li><li>• Do not let yourself run out of medicine over the weekend or on holidays.</li><li>• Do not give Erlotinib Sandoz to anyone else even if they have the same condition as you.</li><li>• Smokers should stop smoking while taking Erlotinib Sandoz as blood levels of Erlotinib Sandoz may be reduced.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Erlotinib Sandoz affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Erlotinib Sandoz in a cool dry place where the temperature stays below 30°C.</li></ul>

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

### 6. Are there any side effects?

**Common side effects:** rash, diarrhoea, tiredness, loss of appetite, cough, nausea or vomiting, dehydration, stomach pain/discomfort or belching after eating, itching, dry skin, infection, folliculitis, nail bed infection or swelling around the nails, headache, rigors or shaking.

**Serious side effects:** mouth irritation, sore mouth, mouth ulcers or cold sores, persistent cough, fever, chills, shortness of breath or difficulty breathing with cough and/or fever, vomiting blood or material that looks like coffee grounds, tongue and/or facial swelling, blisters on your skin, yellow of skin and eyes, dark coloured urine.

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.

# Erlotinib Sandoz®

Active ingredient(s): *erlotinib hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Erlotinib Sandoz. **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 Erlotinib Sandoz.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Erlotinib Sandoz?

**Erlotinib Sandoz contains the active ingredient erlotinib.** Erlotinib Sandoz belongs to a group of medicines called anti-neoplastic (or anti-cancer) agents which are used to treat cancer.

Erlotinib Sandoz prevents the activity of the EGFR protein. This protein is known to be involved in the growth and spread of cancer cells.

**Erlotinib Sandoz is used for the treatment of non-small cell lung cancer (NSCLC).** It can be given before or after initial chemotherapy if your cancer has specific mutations in a protein called epidermal growth factor receptor (EGFR). It can also be given later on when initial chemotherapy has not worked.

**Erlotinib Sandoz is also used in combination with gemcitabine for the treatment of pancreatic cancer.**

Your doctor may have prescribed Erlotinib Sandoz for another purpose.

**Ask your doctor if you have any questions about why Erlotinib Sandoz has been prescribed for you.**

## 2. What should I know before I use Erlotinib Sandoz?

### Warnings

**Do not use Erlotinib Sandoz if:**

- you are allergic to erlotinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- the package is torn or shows signs of tampering

**Check with your doctor if you:**

- have any other medical conditions
  - liver problems. It is not known whether Erlotinib Sandoz has a different effect if your liver is not functioning normally.
  - kidney problems
  - history of stomach ulcers or inflammation of the bowel wall
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives
- cannot tolerate lactose

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.**

Erlotinib Sandoz may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Erlotinib Sandoz while you are pregnant.

If you are a woman who could become pregnant use adequate contraception during treatment, and for at least 2 weeks after taking the last tablet.

If you become pregnant while you are being treated with Erlotinib Sandoz, tell your doctor immediately.

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

It is not known whether erlotinib passes into breast milk. It is not recommended that you breast-feed while taking Erlotinib Sandoz and for at least 2 weeks after final dose.

## Use in children

Safety and effectiveness in patients less than 18 years of age have not been established.

## Use in elderly

Reduction in dose is not required for elderly patients.

## 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.

## Some medicines may interfere with Erlotinib Sandoz and affect how it works.

These medicines include:

- medicines used to treat heartburn, indigestion and ulcers, such as antacids, H<sub>2</sub> antagonists (e.g. ranitidine) and proton pump inhibitors (e.g. omeprazole)
- medicines used to treat HIV infection such as atazanavir, indinavir, ritonavir and saquinavir
- medicines used to treat epilepsy such as carbamazepine, phenobarbital (also known as phenobarbitone), phenytoin and midazolam
- medicines used to treat bacterial infections such as ciprofloxacin, clarithromycin, erythromycin, rifampicin and rifabutin
- corticosteroids, a group of medicines used to treat inflammation
- medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole
- midazolam, a medicine used to cause drowsiness before an operation
- non-steroidal anti-inflammatory medicines (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- statins, a group of medicines used to lower cholesterol
- other medicines used to treat cancer

There are some medicines that may still be taken with Erlotinib Sandoz but may require close supervision by your doctor. These medicines include:

- warfarin, a medicine used to prevent blood clots

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

## 4. How do I use Erlotinib Sandoz?

### How much to take

- Take Erlotinib Sandoz exactly as your doctor has prescribed. Your doctor will tell you how many Erlotinib Sandoz tablets to take each day.
- For non-small-cell lung cancer, the usual dose is one 150 mg tablet each day.
- For pancreatic cancer, given in combination with gemcitabine, the usual dose is one 100 mg tablet each day.

### When to take Erlotinib Sandoz

- Erlotinib Sandoz should be taken:
  - at least 1 hour before you eat or
  - at least 2 hours after you have eaten
- Do not take Erlotinib Sandoz with food.

### How to take Erlotinib Sandoz

- Swallow the tablets whole with a glass of water.
- Do not chew the tablets.

## How long to take Erlotinib Sandoz

- The duration of treatment with Erlotinib Sandoz varies, depending on the nature of your illness and your individual response to the treatment.
- Continue taking Erlotinib Sandoz until your doctor tells you to stop.

## If you forget to use Erlotinib Sandoz

Erlotinib Sandoz should be used regularly at the same time each day. If you miss a dose:

**Do not take an extra dose. Wait until the next dose and take your normal dose then.**

**Do not try to make up for the dose that you missed by taking more than one dose at a time.**

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

## If you use too much Erlotinib Sandoz

If you think that you have used too much Erlotinib Sandoz, 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 Erlotinib Sandoz?

### Things you should do

- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- Tell your doctor if you feel the tablets are not helping your condition.
- Be sure to keep all of your appointments with your doctor so that your progress can be checked.

### Call your doctor straight away if you:

- become pregnant while taking Erlotinib Sandoz.

Remind any doctor, dentist or pharmacist you visit that you are using Erlotinib Sandoz.

### Things you should not do

- Do not stop taking Erlotinib Sandoz or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give Erlotinib Sandoz to anyone else even if they have the same condition as you.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

- Smokers should stop smoking while taking Erlotinib Sandoz as blood levels of Erlotinib Sandoz may be reduced.

### Driving or using machines

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

It is not known if Erlotinib Sandoz will affect your ability to drive or use machines.

### Looking after your medicine

- Keep your tablets in their container until it is time to take them.  
If you take the tablets out of their container they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight below 30°C; 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.**

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 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
<p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>rash</li> <li>itching</li> <li>dry skin</li> <li>acne</li> <li>tear in the skin</li> <li>folliculitis (infection of the hair roots)</li> <li>unusual hair loss or thinning</li> <li>nail bed infection or swelling around the nails</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>diarrhoea (your doctor may need to treat you with a</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>They are generally mild and do not cause patients to stop taking Erlotinib Sandoz.</b></p>

<p>medicine for this e.g. loperamide)</p> <ul style="list-style-type: none"> <li>nausea or vomiting</li> <li>stomach pain or discomfort or belching after eating</li> </ul> <p><b>General disorders:</b></p> <ul style="list-style-type: none"> <li>tiredness</li> <li>dehydration (signs include dry skin, dark coloured urine, thirst, weakness or fatigue and loss of appetite)</li> <li>headache</li> <li>fever</li> <li>rigors or shaking</li> </ul> <p><b>Metabolism and nutrition related:</b></p> <ul style="list-style-type: none"> <li>loss of appetite</li> <li>weight loss</li> </ul> <p><b>Lungs related:</b></p> <ul style="list-style-type: none"> <li>difficulty in breathing</li> <li>cough</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>conjunctivitis, discharge with itching of the eyes and crusty eyelid or swollen runny eyes</li> <li>irritation or feeling of having something in the eye</li> <li>inflammation of the eye, including pain or redness, sensitivity to light or reduced vision</li> </ul> <p><b>Others:</b></p> <ul style="list-style-type: none"> <li>infection</li> <li>nose bleeds</li> <li>depression</li> <li>numbness or weakness of the arms and legs</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>mouth irritation, sore mouth, mouth ulcers or cold sores</li> <li>persistent cough</li> <li>infection, fever, chills</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>severe stomach pain or discomfort</li> <li>severe or persistent diarrhoea, nausea, vomiting or loss of appetite</li> <li>vomiting blood or material that looks like coffee grounds, bleeding from your back</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>

<p>passage, black sticky bowel motions (stools), bloody diarrhoea</p> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>tongue and/or facial swelling</li> <li>hives</li> <li>wheezing</li> <li>shortness of breath or difficulty breathing with cough and/or fever.</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>blisters on your skin, especially severe blisters and bleeding in the lips, eyes, mouth, nose and genitals</li> <li>painful red areas of skin, large blisters and/or peeling of layers of skin, accompanied by fever and chills, aching muscles and generally feeling unwell</li> </ul> <p><b>Liver related:</b></p> <ul style="list-style-type: none"> <li>yellowing of the skin and eyes</li> <li>dark coloured urine</li> </ul>	
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**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 Erlotinib Sandoz contains

<b>Active ingredient (main ingredient)</b>	erlotinib
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>lactose monohydrate</li> <li>microcrystalline cellulose</li> <li>sodium starch glycollate</li> <li>magnesium stearate</li> <li>isopropyl alcohol</li> </ul> <p>The tablets have a film-coating which contains:</p>

	<ul style="list-style-type: none"> <li>Opadry 200 Optimised Performance Coating 200F280000 White</li> </ul>
<b>Potential allergens</b>	lactose

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

### What Erlotinib Sandoz looks like

Erlotinib Sandoz 25 mg– white to yellowish, round, biconvex film-coated tablets with "25" engraved on one side (Aust R 326623).

Erlotinib Sandoz 100 mg– white to yellowish, round, biconvex film-coated tablets with "100" engraved on one side (Aust R 326624).

Erlotinib Sandoz 150 mg– white to yellowish, round, biconvex film-coated tablets with "150" engraved on one side (Aust R 326622).

Each tablet strength comes in packs of 30 tablets.

### Who distributes Erlotinib Sandoz

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia

Tel 1800 726 369

This leaflet was prepared in December 2025.

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