

Erlocip Film Coated Tablet

Consumer Medication Information (RiMUP)

Erlotinib (25 mg, 100 mg and 150 mg)

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What Erlocip is used for

Erlocip contains the active ingredient erlotinib.

Erlocip is indicated for adults. This medicine can be prescribed to you if you have non-small cell lung cancer at an advanced stage. It can be prescribed as initial therapy if your cancer cells have specific EGFR mutations. It can also be prescribed if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

Erlocip is also used in combination with gemcitabine for the treatment of pancreatic cancer.

This medicine is available only with a doctor's prescription.

How Erlocip works

As a targeted cancer treatment, Erlocip targets a specific protein on the surface of the cancer cells called EGFR / HER1 (epidermal growth factor receptor 1). It slows or blocks the activity of EGFR and may cause the cancer cells to die, with potentially less damage to normal cells.

However, the way Erlocip works to treat cancer is not fully known.

Before you take Erlocip

- When you must not take it

Do not take Erlocip if:

1. you have had an allergic reaction to Erlocip or any ingredients listed at the end of this leaflet.
2. the package is torn or shows signs of tampering.
3. the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking Erlocip, talk to your doctor.

Use in children

Do not give Erlocip to children.

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

- Before you start to take it

Your doctor must know about all the following before you start to take Erlocip.

Tell your doctor if:

1. you are pregnant or plan to become pregnant

Erlocip may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Erlocip 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 Erlocip, tell your doctor immediately.

2. you are breast-feeding or plan to breast-feed

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

3. you have liver problems

It is not known whether Erlocip has a different effect if your liver is not functioning normally.

4. you have kidney problems

5. you have a history of stomach ulcers or inflammation of the bowel wall

6. you are allergic to any other medicines, foods, dyes or preservatives

7. you cannot tolerate lactose

If you have not told your doctor about any of the above, tell them before you start taking Erlocip.

- Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Erlocip. These medicines include:

- antacids, medicines used to treat heartburn and indigestion
- ciprofloxacin, a medicine used to treat bacterial infection
- corticosteroids, a group of medicines used to treat inflammation
- erythromycin, a medicine used to treat bacterial infection
- H₂ antagonists, a group of medicines used to treat stomach ulcers or reflux
- ketoconazole, a medicine used to treat fungal infection
- midazolam, a medicine used to induce drowsiness before an operation
- non-steroidal anti-inflammatory medicines (NSAIDs), a group of medicines commonly used as pain killers
- statins, a group of medicines used to lower cholesterol
- omeprazole, a medicine used for indigestion or stomach ulcers
- rifampicin and rifabutin, medicines used to treat bacterial infection

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- other medicines used to treat cancer

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

- warfarin, a medicine used to thin the blood

Your doctor will need to regularly monitor you with blood tests.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Erlocip.

In addition, grapefruit and grapefruit juice have an effect on how Erlocip works. Do not eat grapefruit or drink grapefruit juice while on treatment with Erlocip, except under the care of your doctor.

How to take Erlocip

- How much to take

Take Erlocip exactly as your doctor has prescribed.

Your doctor will tell you how many Erlocip 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 it

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

Take Erlocip tablet at least 1 hour before you eat or at least 2 hours after you have eaten. Do not take Erlocip with food.

- How long to take Erlocip

The duration of treatment with Erlocip varies, depending on the nature of your illness and your individual response to the treatment.

Continue taking Erlocip until your doctor tells you to stop.

- If you forget to take Erlocip

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 take too much (overdose)

Contact your doctor or pharmacist immediately.

You may have increased side effects and your doctor may interrupt your treatment.

While you are using Erlocip

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Erlocip.

Tell your doctor if you become pregnant while taking Erlocip.

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.

- Things you must not do

Do not stop taking Erlocip 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 Erlocip 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.

Smoking may affect how well Erlocip works for you. If you smoke, you should stop smoking before starting treatment with Erlocip. Talk with your doctor about how to quit smoking. If you continue to smoke, you should talk to your doctor before taking Erlocip.

- Things to be careful of

It is very unlikely that Erlocip will affect your ability to drive or use machines.

Be careful driving or operating machinery until you know how Erlocip affects you.

Side effects

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

Erlocip helps people with non-small cell lung cancer and pancreatic cancer but it may have unwanted side effects.

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.

The most common side effects in patients who took Erlocip were generally mild to moderate rash and diarrhoea. You may also have other changes in your skin.

The rash from Erlocip therapy may appear on your upper body or face. Typically rash occurs within 8 days of starting treatment, but it may occur any time during treatment with Erlocip. The rash is not an allergic reaction. It may look like acne or dry skin. It is not acne.

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Some suggestions to prevent rash are early use of alcohol-free moisturizer, avoidance of direct sunlight exposure and use a high-factor sunscreen whenever you are outdoors. However, talk to your doctor if a rash occurs.

Hair and nail changes have also been seen with Erlocip, but mostly are non-serious.

Typically, diarrhea may develop within 12 days of starting Erlocip. Diarrhoea is manageable with rehydration, erlotinib dose adjustment and medication as per your doctor's recommendation. Therefore, talk to your doctor if diarrhoea occurs.

Others may occur in some people and there may be some side effects not yet known.

Tell your doctor immediately if you have these signs or symptoms:

- New or worsening skin rash
- Serious or ongoing diarrhoea, nausea, loss of appetite, or vomiting
- New or worsening shortness of breath or cough
- Eye irritation

Tell your doctor if you notice anything else that is making you feel unwell.

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

Storage and Disposal of Erlocip

- Storage

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.

Keep Erlocip in a cool dry place where the temperature stays below 30°C.

Keep Erlocip where young children cannot reach it.

- Disposal

If your doctor tells you to stop taking Erlocip, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

- What it looks like

Erlocip 25

White, round, biconvex, film coated tablet debossed with 'C1' on one side and plain on the other.

Erlocip 100

White, round, biconvex, film coated tablet debossed with 'C2' on one side and plain on the other.

Erlocip 150

White, round, biconvex, film coated tablet debossed with 'C3' on one side and plain on the other.

- Ingredients

Active ingredient:

- Erlotinib

Inactive ingredient:+

- microcrystalline cellulose,
- lactose monohydrate,
- sodium starch glycolate,
- sodium lauryl sulfate,
- magnesium stearate,
- purified water
- opadry 20B58900 white (Hypromellose, titanium oxide, hydroxypropyl cellulose, macrogol / PEG)

- MAL Number

Erlocip 25 MALXXXXXXXXX

Erlocip 100 MALXXXXXXXXX

Erlocip 150 MALXXXXXXXXX

- Pack Size

1 x 10 Tablets

Manufacturer

CIPLA LTD.

S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-143/3 & L147/A
Verna Industrial Estate,
Verna – Goa

Product Registration Holder

CIPLA MALAYSIA SDN BHD

Suite 1101, Amcorp Tower
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18, Persiaran Barat, 46050
Petaling Jaya, Selangor, Malaysia

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