

ERLOTINIB integra Film-coated Tablets

Erlotinib (100mg and 150mg)

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What ERLOTINIB integra is used for?

ERLOTINIB integra contains the active ingredient erlotinib.

ERLOTINIB integra 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.

ERLOTINIB integra is also used in combination with *gemcitabine* for the treatment of pancreatic cancer.

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

How ERLOTINIB integra works?

As a targeted cancer treatment, Erlotinib 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 Erlotinib works to treat cancer is not fully known.

Before you use ERLOTINIB integra

When you must not take it

Do not take Erlotinib if:

- you have had an allergic reaction to Erlotinib or any ingredients listed at the end of this leaflet
- the package is torn or shows signs of tampering
- 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 Erlotinib, talk to your doctor.

Use in children:

Do not give Erlotinib to children. Safety and effectiveness in patients less than 18 years of age have not been established.

Before you start to use it

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

Tell your doctor:

- you are pregnant or plan to become pregnant

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

- If 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 Erlotinib.

- If you have liver problems

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

- If you have kidney problems
- If you have a history of stomach ulcers or inflammation of the bowel wall

- If you are allergic to any other medicines, foods, dyes or preservatives

If you cannot tolerate lactose
If you have not told your doctor about any of the above, tell them before you start taking Erlotinib.

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 Erlotinib. 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 Erlotinib 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 Erlotinib.

How to use ERLOTINIB integra?

How much to use

Take Erlotinib exactly as your doctor has prescribed. Your doctor will tell you how many Erlotinib 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.

How to use it

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to use it

Take Erlotinib tablets:

at least 1 hour before you eat or at least 2 hours after you have eaten

Do not take Erlotinib with food.

How long to it

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

Continue taking Erlotinib until your doctor tells you to stop.

If you forget to use it

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 ERLOTINIB integra

Things you must do

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

Tell your doctor if you become pregnant while taking Erlotinib.

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 Erlotinib 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 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 Erlotinib works for you. If you

smoke, you should stop smoking before starting treatment with Erlotinib. Talk with your doctor about how to quit smoking. If you continue to smoke, you should talk to your doctor before taking Erlotinib.

Things to be careful of

It is very unlikely that Erlotinib will affect your ability to drive or use machines. Be careful driving or operating machinery until you know how Erlotinib affects you.

Side Effects

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

Erlotinib 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 very common side effects in patients who took Erlotinib were infection, anorexia, weight decrease, pinkeye, dry eye, depression, headache, neuropathy, shortness of breath, cough, diarrhea, nausea, vomiting, inflamed and sore mouth, stomach pain, indigestion, flatulence, rash, itching, dry skin, hair loss, tiredness, fever and chills.

The rash from Erlotinib therapy may appear on your upper body or face. The rash is not an allergic reaction. It may look like acne or dry skin. It is not acne.

Some suggestions to prevent rash

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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 Erlotinib, but mostly are non-serious.

Please see the Erlotinib full prescribing information for complete safety information. 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 or adverse 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 ERLOTINIB integra

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

Keep Erlotinib where young children cannot reach it.

If your doctor tells you to stop

taking Erlotinib, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What ERLOTINIB INTEGA looks like

ERLOTINIB INTEGA 100 mg tablets are white to yellowish, round biconvex, film-coated tablet, engraved “100” on one side.

ERLOTINIB INTEGA 150 mg tablets are white to yellowish, round biconvex, film-coated tablet, engraved “150” on one side.

ERLOTINIB INTEGA is available in two strengths, 100 mg and 150 mg.

Each tablet strength comes in packs of 30 tablets.

Ingredients

Active ingredient

erlotinib

Inactive ingredients

- lactose monohydrate
 - cellulose microcrystalline
 - sodium starch glycolate
 - magnesium stearate.
- The tablets have a film-coating which contains:
- poly (vinyl alcohol)
 - titanium dioxide
 - macrogol
 - talc
 - methacrylic acid- ethyl acrylate copolymer
 - sodium hydrogen carbonate

MAL number

- ERLOTINIB integra 100 mg film-coated tablet
MAL21086012ACZ
- ERLOTINIB integra 150 mg film-coated tablet
MAL21086011ACZ

Manufacturer

Remedica Ltd.
Aharnon Street,
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Product Registration Holder

Intega Sdn. Bhd.
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