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Erlotinib

Erlotinib

Generic name: erlotinib
Brand name: Tarceva
Dosage form: oral tablet
Drug class: EGFR inhibitors

Medically reviewed by Philip Thornton, DipPharm. Last updated on Mar 25, 2025.

Uses Warnings Before taking Dosage Side effects Interactions FAQ

What is erlotinib?

Erlotinib is a type of targeted therapy used to treat cancer.

Erlotinib is a tyrosine kinase inhibitor that works by blocking the kinase activity of a protein called epidermal growth factor receptor (EGFR), which is involved in cell growth and survival.

EGFR is found on the surface of normal and cancerous cells. Sometimes normal versions of the EGFR protein can contribute to the development of cancer, but in other cases mutations can occur in the EGFR protein, which enable cancer cells to grow, divide and spread faster.

Erlotinib is used to treat pancreatic cancer and non-small cell lung cancer (NSCLC). It is only used to treat cases of NSCLC that have specific mutations in their EGRF protein - exon 19 deletions or exon 21 substitution mutations.

Erlotinib was first approved by the US Food and Drug Administration (FDA) in 2004. It is available under the brand name Tarceva and also as a generic tablet.

What is erlotinib used for?

Erlotinib is a prescription medication used:

- For the treatment of patients with metastatic (cancer that has spread) NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations who are receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.
 - You healthcare provider will use an FDA-approved test to check if you have one of these mutations. The safety
 and efficacy of erlotinib has not been established in patients with NSCLC whose tumors have other EGFR
 mutations.
- In combination with gemcitabine in patients with advanced-stage pancreatic cancer whose cancer has spread, grown, or cannot be surgically removed and who have not received previous chemotherapy (first-line).

Erlotinib tablets are not recommended for use in combination with platinum- based chemotherapy.

Important information

Erlotinib can cause serious side effects, including

- Lung problems called interstitial lung disease events. Erlotinib has been shown to cause lung problems, including
 death. Symptoms of lung problems may include shortness of breath, cough, and fever. Erlotinib may need to be
 stopped if you have any of these symptoms.
- Liver and kidney problems. Erlotinib has been shown to cause severe kidney and liver problems, including death.
 Some people had their kidneys and liver stop working. Let your healthcare provider know if you have a history of liver or kidney disease.
- Stomach and intestinal problems called gastrointestinal perforation. Erlotinib has been shown to cause gastrointestinal perforation, which has led to death. A gastrointestinal perforation is a hole that develops in your stomach or intestine. Erlotinib patients may be at a higher risk for gastrointestinal perforation if they:
 - Are taking medicines including those that may help block the growth of blood vessels; steroids; non-steroidal
 anti-inflammatory drugs (NSAIDs); and certain chemotherapies. Always tell your healthcare provider about any
 medicines you are taking.
 - Have a history of ulcers or other stomach disease.
- Serious skin conditions. Erlotinib has been shown to cause blistering and skin peeling. This may result in other serious skin disorders or death.
- Blood, bleeding, and clotting problems. Erlotinib has been shown to cause certain blood problems and other bleeding and clotting problems. These have led to stroke and death.
- Eye disorders. Erlotinib has been shown to cause dry eyes, unusual eyelash growth, or swelling of the cornea. The cornea is the clear coating of the eyeball. This swelling may irritate or damage the eye.
- Bleeding events when taking warfarin with erlotinib. Tell your healthcare provider if you are taking a blood thinner, such as warfarin. Taking erlotinib with this medicine can cause death.
- Pregnancy. Erlotinib can harm an unborn baby. Women should use effective birth control during treatment and for at least 1 month after the last dose of erlotinib. Tell your healthcare provider if you have become pregnant, or if you think you may be pregnant, during treatment with erlotinib. Do not breast-feed during treatment with erlotinib and for 2 weeks after the final dose.

Call your healthcare provider if you experience the following while taking erlotinib:

- Serious or ongoing diarrhea, nausea (feeling sick to your stomach), loss of appetite, or vomiting.
- New or worsening shortness of breath or cough.
- Eye irritation.
- New or worsening rash, blistering, or peeling of the skin.
- Any changes in smoking habits.

Who should not take erlotinib?

Do not take erlotinib if you are allergic to erlotinib or any of the ingredients in it. See below for a complete list of ingredients.

Erlotinib pregnancy and breastfeeding warnings (more detail)

What should I tell my doctor before taking erlotinib?

Before you take erlotinib, tell your doctor about all of your medical conditions.

Tell your doctor if you smoke before starting erlotinib.

How should I take erlotinib?

- Take erlotinib tablets exactly as prescribed by your healthcare provider.
- Take erlotinib once daily.
- Take erlotinib on an empty stomach, one hour before food or two hours after food.

What should I avoid while taking erlotinib?

- Erlotinib can cause a rash that can occur or get worse when exposed to sunlight. Avoid being out in the sun if it causes a rash.
- Avoid smoking while taking erlotinib. Your treatment with erlotinib may need to be adjusted if you smoke. Talk with
 your healthcare provider if you smoke while taking erlotinib.

Dosing information

The recommended dose of erlotinib is:

- 150 mg once daily in patients with NSCLC.
- 100 mg once daily in patients with pancreatic cancer.

Erlotinib should be taken on an empty stomach.

Detailed Erlotinib dosage information

What are the side effects of erlotinib?

Erlotinib can cause serious side effects including:

• See "Important information" above.

Erlotinib can cause skin, hair and nail problems:

- While taking erlotinib a rash could appear or get worse if the skin is exposed to the sun. You may want to use alcohol-free lotions and sunscreens or avoid being out in the sun.
- Your skin and nails may get darker while taking erlotinib. You may also have dry skin that may or may not crack.

This most often happens with rash.

• You may get more hairy and develop brittle or loose nails.

The most common side effects of erlotinib in patients with NSCLC who had not received previous chemotherapy are:

- diarrhea
- weakness
- rash
- cough
- · shortness of breath
- loss of appetite (not wanting to eat)

The most common side effects of erlotinib in patients with NSCLC receiving it as maintenance, 2nd or 3rd line therapy are:

- rash
- diarrhea

The most common side effects of erlotinib in patients with pancreatic cancer are:

- fatigue (feeling very tired)
- rash
- nausea
- · loss of appetite
- diarrhea

These are not all of the possible side effects with erlotinib. Call your doctor for medical advice about side effects. Talk to your doctor about any side effects that bother you or do not go away.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

<u>Erlotinib side effects</u> (more detail)

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Interactions

Erlotinib can interact with a number of other medications. You may need to adjust the dose or timing of erlotinib or your other medications. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Talk to your healthcare provider before taking any new medicines or supplements.

Do not eat grapefruit or drink grapefruit juice before talking with your healthcare provider.

fi Erlotinib drug interactions (more detail)

Does erlotinib interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

erlotinib
+
Enter a drug name
Add

Pregnancy and breastfeeding

Erlotinib can harm an unborn baby. Women should use effective birth control during treatment and for at least 1 month after the last dose of erlotinib. Tell your healthcare provider if you have become pregnant, or if you think you may be pregnant, during treatment with erlotinib.

Do not breastfeed during treatment with erlotinib and for 2 weeks after the final dose.

Storage

• Store erlotinib at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Keep out of reach of children.

What are the ingredients in erlotinib?

Active ingredients: erlotinib hydrochloride

Inactive ingredients in Tarceva: lactose monohydrate, hypromellose, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, sodium lauryl sulfate and titanium dioxide.

Other generic versions of erlotinib may have different inactive ingredients. Check the product label for the version of erlotinib you take for a complete list of ingredients.

Erlotinib is distributed under the brand name Tarceva by Genentech USA, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990. Generic versions of erlotinib are also manufactured by a number of other companies.

Popular FAQ

How does erlotinib work (mechanism of action)?

Can Tarceva (erlotinib) cure lung cancer?

References

- 1. National Library of Medicine Erlotinib (Teva Pharmaceuticals) Product Label
- 2. National Library of Medicine Erlotinib (Areva Pharmaceuticals) Product Label
- 3. National Library of Medicine Erlotinib (Alembic Pharmaceuticals) Product Label
- 4. Food and Drug Administration (FDA) Tarceva Product Label

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- · Check interactions
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Other brands

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Professional resources

- Erlotinib monograph
- Erlotinib Tablets (FDA)

Other brands

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Related treatment guides

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- Pancreatic Cancer
- Renal Cell Carcinoma

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability Rx Prescription only Pregnancy & Lactation Risk data available CSA Schedule* N/A Not a controlled drug Approval History

Drug history at FDA

User Reviews & Ratings

8.4 / 10

45 Reviews

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Erlotinib Hydrochloride 100 mg (S12)





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