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2. Lapatinib

Lapatinib

Generic name: lapatinib [la-PA-tin-ib]

Brand name: Tykerb

Dosage form: oral tablet (250 mg)

Drug classes: EGFR inhibitors, HER2 inhibitors



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What is lapatinib?

Lapatinib is used to treat advanced hormone-related breast cancer that has progressed or spread after treatment with other cancer medicines.

Lapatinib is used for this condition only if your tumor tests positive for a protein called human epidermal growth factor receptor 2 (HER2). HER2 protein can speed the growth of cancer cells.

In postmenopausal women, lapatinib is given in combination with a hormonal medicine called letrozole (Femara). In others, lapatinib is given together with a cancer medicine called capecitabine (Xeloda).

Lapatinib may also be used for purposes not listed in this medication guide.

Lapatinib side effects

Get emergency medical help if you have **signs of an allergic reaction** (hives, difficult breathing, swelling in your face or throat) **or a severe skin reaction** (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).

Lapatinib can cause severe or fatal liver problems. **Call your doctor right away if you have:** upper stomach pain, itching, dark urine, clay-colored stools, or jaundice (yellowing of the skin or eyes).

Also call your doctor at once if you have:

- fast or pounding heartbeats, fluttering in your chest, shortness of breath, and sudden dizziness (like you might pass out);
- severe or ongoing diarrhea; or
- new or worsening cough, wheezing, chest pain, feeling short of breath.

Common side effects of lapatinib may include:

- · indigestion, loss of appetite;
- nausea, vomiting, diarrhea;
- · rash, itching, dry skin, acne;
- pain or redness on the palms of your hands or the soles of your feet;
- problems with your fingernails or toenails;
- · feeling weak or tired;
- nosebleeds, mouth sores;
- · thinning hair; or
- · headache.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Lapatinib side effects (more detail)

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Warnings

Do not use lapatinib if you are pregnant. It could harm the unborn baby.

Lapatinib can cause severe or fatal liver problems. Call your doctor at once if you have: upper stomach pain, itching, dark urine, clay-colored stools, or jaundice (yellowing of the skin or eyes).

Before taking this medicine

You should not use lapatinib if you are allergic to it.

Tell your doctor if you have ever had:

- heart disease:
- liver disease (lapatinib can cause severe or fatal liver problems);
- an electrolyte imbalance (such as low levels of potassium or magnesium in your blood); or
- long QT syndrome (in you or a family member).

You may need to have a negative pregnancy test before starting this treatment.

Both men and women using lapatinib should use effective birth control to prevent pregnancy. Lapatinib can harm an unborn baby or cause birth defects if the mother or father is using this medicine. Keep using birth control for at least 1 week after your last dose.

Tell your doctor right away if a pregnancy occurs while either the mother or the father is using lapatinib.

Do not breast-feed while using this medicine, and for at least 1 week after your last dose.

How should I take lapatinib?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

When used **with letrozole**, the usual dose of lapatinib is 6 tablets taken once daily every day. Letrozole is also taken every day.

When used **with capecitabine**, the usual dose of lapatinib 5 tablets taken once daily for 21 days in a row. Capecitabine is also taken twice daily for only the first 14 days. This 21-day cycle is then repeated.

Follow your doctor's dosing instructions very carefully.

Take lapatinib on an empty stomach, at least 1 hour before or 1 hour after a meal.

You may swallow each lapatinib tablet one at a time, but take the entire dose (all 5 or 6 tablets) at the same time each day.

Capecitabine must be taken with food or within 30 minutes of eating.

You will need blood tests every 4 to 6 weeks to check your liver function. Your heart function may also need to be checked using an electrocardiograph or ECG (sometimes called an EKG).

Store lapatinib at room temperature away from moisture and heat. Keep the bottle tightly closed when not in use.

Your doctor will determine how long to treat you with lapatinib and capecitabine or letrozole. Take your medications for the full prescribed length of time. Combination chemotherapy is usually continued unless your condition gets worse or you have serious side effects.

Lapatinib dosing information

Usual Adult Dose for Breast Cancer:

HER2-Positive Metastatic Breast Cancer (in combination with capecitabine):

1250 mg orally once a day on Days 1 to 21 continuously in repeating 21-day cycles in combination with capecitabine 2000 mg/m2/day (administered orally in 2 doses approximately 12 hours apart) on Days 1 to 14 in a repeating 21-day cycle

Hormone Receptor-Positive, HER2-Positive Metastatic Breast Cancer (in combination with letrozole): 1500 mg orally once a day continuously in combination with letrozole 2.5 mg orally once a day

Comments:

- -The dose of this drug should be once daily (5 tablets administered all at once); do not divide the daily dose. is not recommended [see Clinical Pharmacology (12.3)]. Capecitabine should be taken with food or within 30 minutes after food. If a day's dose is missed, the patient should not double the dose the next day. Treatment should be continued until disease progression or unacceptable toxicity occurs.
- -HER2-positive metastatic breast cancer patients should have disease progression on trastuzumab prior to initiation of therapy with this drug in combination with capecitabine.

Uses:

- -In combination with capecitabine for treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.
- -In combination with letrozole for treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.
- 1 Detailed Lapatinib dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. **Do not** take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking lapatinib?

Grapefruit may interact with lapatinib and lead to unwanted side effects. Avoid the use of grapefruit products.

What other drugs will affect lapatinib?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Many drugs can affect lapatinib. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed here. Tell your doctor about all your current medicines and any medicine you start or stop using.

Lapatinib drug interactions (more detail)

Does lapatinib interact with my other drugs?

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

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+	
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Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

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

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ঝ্য Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

Drug history at FDA

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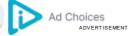
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