

[Home](#) → [Drugs, Herbs and Supplements](#) → Afatinib

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Afatinib

pronounced as (a fa' ti nib)

Why is this medication prescribed?

Afatinib is used to treat certain types of non-small cell lung cancer that has spread to nearby tissues or to other parts of the body. Afatinib is in a class of medications called kinase inhibitors. It works by blocking the action of a certain naturally occurring substance that may be needed to help cancer cells multiply.

How should this medicine be used?

Afatinib comes as a tablet to take by mouth. It is usually taken on an empty stomach once a day, at least 1 hour before or 2 hours after eating a meal or snack. Take afatinib at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take afatinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor may temporarily or permanently stop your treatment or decrease the dose if you experience serious side effects of afatinib. Talk to your doctor about how you are feeling during your treatment.

Continue to take afatinib even if you feel well. Do not stop taking afatinib without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking afatinib,

- tell your doctor and pharmacist if you are allergic to afatinib, any other medications, or any of the ingredients in afatinib tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: amiodarone (Cordarone, Pacerone); certain antifungal medications such as itraconazole (Sporanox) and ketoconazole (Nizoral); cyclosporine (Gengraf, Neoral, Sandimmune); erythromycin (E.E.S., Erythrocin, others); certain medications for human immunodeficiency virus (HIV) such as nelfinavir

(Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); certain medications for seizures such as carbamazepine (Carbatrol, Equetro, Tegretol), phenobarbital, and phenytoin (Dilantin); quinidine (in Nuedexta); rifampin (Rimactane, Rifadin, in Rifater); tacrolimus (Prograf); and verapamil (Calan, Covera, Isoptin, Verelan). Many other medications may also interact with afatinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you are of Asian descent or have or have ever had lung or breathing problems (other than lung cancer); eye problems, including dry eyes; heart problems; liver or kidney disease; or any other medical condition. Also, tell your doctor if you wear contact lenses.
- tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while you are taking afatinib and for at least 2 weeks after your treatment. Talk to your doctor about birth control methods that you can use during your treatment. If you become pregnant while taking afatinib, call your doctor immediately. Afatinib may harm the fetus.
- tell your doctor if you are breast-feeding. You should not breast-feed while you are taking afatinib.
- plan to avoid unnecessary or prolonged exposure to sunlight and to wear protective clothing, sunglasses, and sunscreen. Afatinib may make your skin sensitive to sunlight. Exposure to sunlight increases the risk that you will develop a rash or acne during your treatment with afatinib.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is less than 12 hours before you are scheduled to take your next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Afatinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- cracking or swelling of the lips or sores in the corners of the mouth
- dry skin or itching
- loss of appetite
- nail infection
- acne
- nose bleeds

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, stop taking afatinib and call your doctor immediately or get emergency medical treatment:

- diarrhea
- dry mouth, dark urine, decreased sweating, dry skin, and other signs of dehydration
- decreased urination
- swelling of the arms, hands, feet, ankles, or lower legs
- rash
- pain, redness, peeling, or blistering of skin
- difficulty breathing
- shortness of breath
- rapid, irregular, or pounding heartbeat
- sudden weight gain
- cough
- fever
- excessive tiredness
- pain in the right upper part of the stomach
- unusual bruising or bleeding
- nausea
- vomiting
- yellowing of the skin or eyes
- dark urine
- red, swollen, painful, or teary eyes
- sudden changes in vision, including blurred vision
- sensitivity to light

Afatinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light, excess heat, and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the

best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- nausea
- vomiting
- weakness
- dizziness
- headache
- stomach pain

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to afatinib.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Gilotrif[®]

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