

Afatinib (Gilotrif)

About This Drug

Afatinib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Decreased appetite (decreased hunger)
- Rash, including a pimple like rash
- Dry skin
- Itching
- Inflammation/infection of the tissue around your nails

Note: Each of the side effects above was reported in 20% or greater of patients treated with afatinib. Not all possible side effects are included above.

Warnings and Precautions

- Severe skin reactions. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful. Your skin may be weepy and peel.
- Inflammation (swelling) and/or scarring of the lungs. You may have a cough and/or trouble breathing.
- Changes in your liver function, which can cause liver failure and can be life-threatening.
- Severe diarrhea which can cause dehydration (lack of water in the body from losing too much fluid) and changes in kidney function, which can be life-threatening.
- Inflammation in your eye, which may cause blurred vision, eye irritation, sensitivity to light and/or other changes in eyesight
- Risk of perforation - an abnormal hole in your stomach, intestine, esophagus, or other organ, which can be life-threatening.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- Your doctor may prescribe you medication to decrease your diarrhea. Please call your doctor and/or nurse as soon as you develop diarrhea and/or if your diarrhea does not improve or becomes worse.
- This medication may increase your sensitivity to the sun. You may get a skin rash/reaction or severe sunburn if you are in the sun or are exposed to sunlamps or tanning beds.

How to Take Your Medication

- Take this medicine by mouth without food, at least 1 hour before you eat or 2 hours after you eat.
- **Missed dose:** If you miss a dose, take it as soon as you think about it **ONLY** if your next dose is due in more than 12 hours. If your next dose is due in **LESS** than 12 hours, then skip the missed dose and contact your physician.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature. Protect from high humidity and light.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.



- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- Use sunscreen with SPF 30 or higher when you are outdoors even for a short time. Cover up when you are out in the sun. Wear wide-brimmed hats, long-sleeved shirts, and pants. Keep your neck, chest, and back covered.
- To help with itching, moisturize your skin several times a day.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Drug Interactions

- There are no known interactions of afatinib with food. This medication should be taken on an empty stomach.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with afatinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking afatinib as this may lower the levels of the drug in your body, which can make it less effective.
- Avoid or speak with your doctor before using nonsteroidal anti-inflammatory drugs (NSAIDs) like aspirin and ibuprofen, as they may increase the risk of perforation.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Blurred vision or other changes in eyesight
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Red or painful eye
- Sensitivity to light
- Pain in your chest
- Dry cough
- Wheezing and/or trouble breathing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day



- Pain in your mouth or throat that makes it hard to eat or drink
- Difficulty swallowing
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Severe abdominal pain that does not go away
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Develop sensitivity to sunlight/light
- Signs of inflammation/infection (redness, swelling, pain) of the tissue around your nails.
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Decreased or very dark urine
- Swelling of the hands, feet, or any other part of the body
- Weight gain of 5 pounds in one week (fluid retention)
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 2 weeks after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 2 weeks after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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