

Patient Information
GILOTRIF® (JEE-loh-trif)
(afatinib) tablets

What is GILOTRIF?

GILOTRIF is a prescription medicine that is used to treat people with non-small cell lung cancer (NSCLC) that:

- has certain (non-resistant) abnormal epidermal growth factor receptor (EGFR) gene(s). Your healthcare provider will perform a test to make sure that GILOTRIF is right for you.
- has spread to other parts of the body (metastatic), and
- has not been previously treated for metastatic lung cancer

It is not known if GILOTRIF is safe and effective in treating people with lung cancer that has resistant abnormal EGFR genes.

or

is used to treat people with squamous cell lung cancer that:

- has spread to other parts of the body, and
- has been previously treated with chemotherapy that contains platinum.

It is not known if GILOTRIF is safe and effective in children.

Before you take GILOTRIF, tell your doctor about all of your medical conditions, including if you:

- have kidney or liver problems
- have lung or breathing problems other than lung cancer
- have a history of an ulcer, a tear (perforation) in your stomach or intestine, or diverticular disease (inflammation) in parts of your large intestine. **See “What are the possible side effects of GILOTRIF?”**
- have a history of severe dry eye or any other eye problems. Tell your doctor if you wear contact lenses.
- have heart problems
- are pregnant or plan to become pregnant. GILOTRIF can harm your unborn baby.
 - Females who are able to become pregnant should use effective birth control during treatment with GILOTRIF and for at least 2 weeks after your last dose of GILOTRIF. Talk to your doctor about birth control methods that may be right for you.
 - Tell your doctor right away if you become pregnant or think you are pregnant during treatment with GILOTRIF.
- are breastfeeding or plan to breastfeed. It is not known if GILOTRIF passes into your breast milk. Do not breastfeed during treatment with GILOTRIF and for 2 weeks after your last dose of GILOTRIF. Talk to your doctor about the best way to feed your baby if you take GILOTRIF.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. GILOTRIF may affect the way other medicines work, and other medicines may affect the way GILOTRIF works. Taking certain medicines with GILOTRIF may increase your risk of developing a tear (perforation) in your stomach or intestine. **See “What are the possible side effects of GILOTRIF?”**

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

How should I take GILOTRIF?

- Take GILOTRIF exactly as your doctor tells you to take it.
- Your doctor will tell you how many GILOTRIF tablets to take and when to take them. Do not change your dose or stop GILOTRIF unless your doctor tells you to.
- Take GILOTRIF on an empty stomach at least 1 hour before a meal or 2 hours after a meal.
- If you miss a dose of GILOTRIF, take it as soon as you remember. If it is within 12 hours of your next dose, skip the dose and just take your next dose at your regular time. Do not take 2 doses of GILOTRIF at the same time.
- If you take too much GILOTRIF, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking GILOTRIF?

Limit your time in the sun. GILOTRIF can make your skin sensitive to sunlight. You could get or have worsening rash or acne. You could get a severe sunburn. Use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight during treatment with GILOTRIF.

What are the possible side effects of GILOTRIF?

GILOTRIF may cause serious side effects, including:

- **diarrhea.** Diarrhea is common with GILOTRIF and may sometimes be severe. Severe diarrhea can cause loss of too much body fluid (dehydration) and kidney problems that can sometimes lead to death. During your treatment with GILOTRIF, your doctor should prescribe medicines to treat diarrhea. Take this medicine exactly as your doctor tells

you to. Tell your doctor if you have diarrhea. Get medical attention right away if your diarrhea does not go away or becomes severe.

- **skin reactions.** GILOTRIF can cause redness, rash, and acne. It is important to get treatment for skin reactions as soon as you notice them. Take medicines to help skin reactions exactly as your doctor tells you to. Get medical attention right away if you develop severe skin reactions such as peeling or blistering of the skin, or blisters in your mouth.
- **lung or breathing problems.** GILOTRIF may cause inflammation of the lung that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your doctor right away if you have any new or worsening lung problems, or any combination of the following symptoms: trouble breathing or shortness of breath, cough, or fever.
- **liver problems.** GILOTRIF can cause liver problems that can sometimes lead to death. Tell your doctor right away if you have any symptoms of a liver problem which may include:
 - yellowing of your skin or the white part of your eyes (jaundice)
 - dark or brown (tea colored) urine
 - pain on the upper right side of your stomach area (abdomen)
 - bleeding or bruising more easily than normal
 - feeling very tired

Your doctor will do blood tests to check your liver function during your treatment with GILOTRIF.

- **tear (perforation) in your stomach or intestine.** Tears in your stomach or intestine can happen with GILOTRIF and can sometimes lead to death. Your risk of developing a tear in your stomach or intestine may be increased if you:
 - take certain medicines with GILOTRIF including: corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and certain other medicines.
 - have a history of stomach or intestinal ulcers, or if you have had diverticular disease (inflammation in parts of the large intestine).

Get medical help right away if you develop severe stomach-area (abdomen) pain during treatment with GILOTRIF.

- **eye problems.** Tell your doctor right away if you have symptoms of eye problems which may include:
 - eye pain, swelling, redness, or tearing
 - blurred vision
 - sensitivity to light
 - other changes in your vision
- **heart problems.** Tell your doctor right away if you have symptoms of a heart problem which may include:
 - new or worsening shortness of breath while at rest or with activity
 - cough
 - tiredness
 - swelling of your ankles, feet, or legs
 - feeling that your heart is pounding or racing (palpitations)
 - sudden weight gain

Your doctor may change your dose, temporarily stop or permanently stop treatment with GILOTRIF if you have certain side effects.

The most common side effects of GILOTRIF include:

- diarrhea
- rash
- acne
- mouth sores
- nail inflammation
- dry skin
- decreased appetite
- nausea
- vomiting
- itching

GILOTRIF may cause decreased fertility in females and males. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of GILOTRIF. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GILOTRIF?

- Store GILOTRIF at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep GILOTRIF in the original container and keep the container tightly closed.
- Keep GILOTRIF away from moisture and light.
- Safely throw away (discard) any GILOTRIF that is out of date or no longer needed.

Keep GILOTRIF and all medicines out of the reach of children.

General information about GILOTRIF

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use

GILOTRIF for a condition for which it was not prescribed. Do not give GILOTRIF to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for information about GILOTRIF that is written for health professionals.

What are the ingredients in GILOTRIF?

Active ingredient: afatinib

Inactive ingredients: Tablet Core: lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate. **Tablet Coating:** hypromellose, polyethylene glycol, titanium dioxide, talc, polysorbate 80, FD&C Blue No. 2 (40 mg and 30 mg tablets only).

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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