

My Guide

You have been prescribed a treatment called GILOTRIF. In this brochure, you can learn more about how GILOTRIF works and what you can expect from taking it.

Information in this Guide is not intended to replace discussions with your healthcare provider. Contact your healthcare provider if you experience any side effects or have questions about GILOTRIF.



GILOTRIF[®]
(afatinib) tablets

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Understanding Your Disease

Non-Small Cell Lung Cancer

The most common kind of lung cancer

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. It gets its name from the kinds of cells involved. It starts in the cells that line the tubes inside your lungs. In some cases, it can metastasize to other parts of your body. If this happens, it is called metastatic NSCLC, or mNSCLC.

Different types of NSCLC

There are several different types of NSCLC. One type of NSCLC is caused by epidermal growth factor receptor (EGFR) mutations. EGFRs are structures that exist on cell surfaces.

Another type of NSCLC is called squamous cell carcinoma (SqCC). “Squamous” cells are thin, flat cells found in many places in the body, such as in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the lining of the lungs and digestive tract. SqCC affects the squamous cells lining the tissues in the lungs.

You are not alone

Being diagnosed with mNSCLC can be difficult and overwhelming for you and your family. It’s important to keep in mind that you are not alone. With so many people affected by NSCLC, the medical and research communities are continuously working to find new treatments for it.

**NSCLC IS THE MOST COMMON TYPE OF LUNG CANCER.
REMEMBER THAT YOU ARE NOT ALONE**

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Learn About Your Treatment

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.

GILOTRIF is an approved treatment

GILOTRIF was tested in people with mNSCLC who had EGFR mutations. Treatment with GILOTRIF was compared to treatment with chemotherapy.

GILOTRIF was also tested in people with metastatic squamous NSCLC who had undergone platinum-based chemotherapy. In that study, GILOTRIF was compared to another drug called erlotinib.

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How does GILOTRIF work?

GILOTRIF attaches to EGFR molecules that have certain kinds of mutations. It then helps block cancer-causing signals that come from these molecules. If your healthcare provider has prescribed GILOTRIF, it may be because you have been tested and found to have one of these EGFR mutations.

Before you take GILOTRIF, tell your healthcare provider 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.
- have a history of severe dry eye or any other eye problems. Tell your healthcare provider 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 healthcare provider about birth control methods that may be right for you.
 - Tell your healthcare provider 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 healthcare provider about the best way to feed your baby if you take GILOTRIF.

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Tell your healthcare provider 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.

Discuss your medicines and medical conditions with your healthcare provider

GILOTRIF IS APPROVED BASED ON CLINICAL STUDIES

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How to take GILOTRIF



GILOTRIF is a once-daily oral tablet

GILOTRIF is a tablet that should be taken once every 24 hours with water, at the same time every day. Take GILOTRIF exactly as your healthcare provider tells you to take it.



Always take GILOTRIF on an empty stomach

Take GILOTRIF on an empty stomach at least 1 hour before a meal or 2 hours after a meal.



What to do if you miss a GILOTRIF dose

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 healthcare provider or go to the nearest hospital emergency room right away.

Remember, do not take GILOTRIF with food.

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Some things your healthcare provider might do if you have side effects

If you have side effects, your healthcare provider may:

- Pause your treatment
- Wait for the side effect to lessen or go away
- Adjust your dose
- Restart your GILOTRIF treatment at a lower dose

Take GILOTRIF exactly as your healthcare provider tells you to take it. Do not stop taking GILOTRIF unless your healthcare provider tells you to stop. If your side effects don't improve after several dose adjustments, or if your symptoms are severe, your healthcare provider may choose to stop your GILOTRIF treatment permanently.



**TAKE GILOTRIF
WITHOUT FOOD**

1 HOUR
BEFORE EATING

OR

2 HOURS
AFTER EATING

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Potential side effects

In a clinical study of GILOTRIF, more than half of the people had their dose adjusted. GILOTRIF was still proven to be effective for them. For many people, side effects got better over time with proper management, such as dose adjustment.

Serious side effects

In some people, GILOTRIF can cause serious side effects, including diarrhea, skin reactions, lung or breathing problems, liver problems, tear (perforation) in your stomach or intestine, eye problems, and heart problems.

Common side effects associated with GILOTRIF

The most common side effects of GILOTRIF include diarrhea, rash, acne, mouth sores, nail inflammation, dry skin, decreased appetite, nausea, vomiting, and itching. Both serious and common side effects are discussed in more detail on the following pages.

Dose adjustments are often used to help with side effects

Some people may need to have their GILOTRIF dose adjusted to help with side effects. For instance, your healthcare provider may decide to pause your GILOTRIF treatment and then start treatment again at a lower dose. Don't worry if your healthcare provider decides to adjust your GILOTRIF dose. You and your healthcare provider can work together to find the right dose for you.

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Tell your healthcare provider about side effects right away

Side effects such as diarrhea and skin rash can happen in the first 2 weeks of treatment

- With proper care for your side effects, you may be able to keep taking GILOTRIF
- Tell your healthcare provider about any change in your health, even if it seems unrelated to lung cancer

Always take GILOTRIF as prescribed and do not change the dose unless directed by a physician.

DOSE ADJUSTMENTS MAY HELP WITH SIDE EFFECTS

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Diarrhea

Diarrhea is common with GILOTRIF and may sometimes be severe. If not treated properly, 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 healthcare provider should prescribe medicine to treat diarrhea. Take this medicine exactly as your healthcare provider tells you to.

Talk to your healthcare provider

- When you first experience diarrhea and if diarrhea affects your daily activities
- If you have pain or cramps in your stomach, fever, or dark, concentrated urine
- If you have been treating your diarrhea for 2 days as your healthcare provider instructed but still have at least 4 bowel movements more than what is normal for you each day
- Seek medical attention right away if your diarrhea becomes severe and your diarrhea medicine isn't working

Your healthcare provider may recommend

- Antidiarrheal medicine, such as loperamide
- Pausing your GILOTRIF treatment and adjusting your dose
- After several dose adjustments, or if your symptoms are severe, your healthcare provider may choose to stop GILOTRIF treatment permanently

Always take GILOTRIF exactly as prescribed, and do not change the dose or stop taking it unless told to do so by your healthcare provider.

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Tips on managing diarrhea:



Drink plenty of liquids

Drink plenty of water and other clear liquids (at least 3-4 quarts per day) to prevent dehydration.



Eat simply

Try to eat plain foods like rice, applesauce, bananas, and toast; and as you get better, include pasta, chicken and turkey (without the skin), and eggs.



Keep clean

Diarrhea can cause painful skin damage. Make sure you regularly wash around the rectal area with warm water.

Tell your healthcare provider right away about any side effects you experience.

YOUR HEALTHCARE PROVIDER MAY RECOMMEND CHANGES TO YOUR DIET

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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 healthcare provider 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.

Talk to your healthcare provider

- When you first experience skin problems and/or if it affects your daily activities
- If you have been treating them according to your healthcare provider's instructions but they do not improve
- If you develop severe skin problems, and get medical attention right away

Your healthcare provider may recommend

- Limiting your time in the sun, since GILOTRIF can make your skin sensitive to sunlight; you could get or have worsening rash or acne. You could get a severe sunburn
- Using sunscreen and wearing a hat or clothes to cover your skin while you are taking GILOTRIF, if you must be in sunlight
- Pausing your GILOTRIF treatment and adjusting your dose
- After several dose adjustments, or if your symptoms are severe, your healthcare provider may choose to stop GILOTRIF treatment permanently

Always take GILOTRIF exactly as prescribed, and do not change the dose or stop taking it unless told to do so by your healthcare provider.

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The pictures below can help you describe a rash to your healthcare provider



Mild

- Looks like pus-filled pimples
 - Little itching or pain
 - Limited to 1 area of the body
-



Moderate

- Looks like pus-filled pimples
 - Some itching or pain
 - May spread to more than 1 area of the body
-



Severe

- Looks like pus-filled pimples
- Increased itching and pain
- Has spread to more than 1 area of the body
- May become infected

Tell your healthcare provider right away about any side effects you experience.

**WEAR SUNSCREEN WHEN OUTSIDE (AT LEAST SPF 15),
AND MOISTURIZE REGULARLY**

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Mouth sores

A possible side effect of GILOTRIF is stomatitis. This is an inflammation of the lining of the mouth. It may be accompanied by ulcers (sores or lesions). Be on the lookout for red, sore, or bleeding gums. Also watch for mouth ulcers on the tongue, lips, and on either the roof or the floor of your mouth.

Talk to your healthcare provider

- If you feel uncomfortable or if sore mouth is affecting your daily activities
- If you have been treating it according to your healthcare provider's instructions but it does not improve

Your healthcare provider may recommend

- Soothing mouth rinses, lozenges, and gels
- Pausing your GILOTRIF treatment and adjusting your dose
- After several dose adjustments, or if your symptoms are severe, your healthcare provider may choose to stop GILOTRIF treatment permanently

Always take GILOTRIF exactly as prescribed, and do not change the dose or stop taking it unless told to do so by your healthcare provider.

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Tips on managing mouth sores:



Practice good oral care

Try brushing with a soft toothbrush; use a warm salt water rinse after meals and at bedtime; and avoid mouthwashes containing alcohol.



Eat for comfort

Eat foods that are cold or at room temperature that are soft, soothing, and moist, like soft fruit.



Soothe soreness

Use lip balm or petroleum jelly for dry lips, and ice or ice pops can numb the mouth as needed.

Tell your healthcare provider right away about any side effects you experience.

DAILY RINSES AND LOZENGES CAN BE SOOTHING

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Nail inflammation

A possible side effect of GILOTRIF is paronychia. This is inflammation and infection of the skin that surrounds your nails.

Talk to your healthcare provider

- If you feel uncomfortable or if inflammation is affecting your daily activities
- If you have been treating it according to your healthcare provider's instructions but it does not improve

Your healthcare provider may recommend

- Creams that can be applied to the affected areas
- Antibiotics to fight infections
- Pausing your GILOTRIF treatment and adjusting your dose
- After several dose adjustments, or if your symptoms are severe, your healthcare provider may choose to stop GILOTRIF treatment permanently

Always take GILOTRIF exactly as prescribed, and do not change the dose or stop taking it unless told to do so by your healthcare provider.

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Be on the lookout for red, swollen skin around your fingernails or toenails.



Mild

Nail inflammation begins as tender, red, and inflamed skin on the sides of the nail.



Moderate

As it becomes more severe, pus may collect around the nail and the infection may spread to the skin underneath.



Severe

Eventually, the cuticle and the skin around it may separate from the nail.

Tell your healthcare provider right away about any side effects you experience.

KEEP YOUR FINGERNAILS CLEAN TO AVOID IRRITATION

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Decreased appetite

- Eat 5 or 6 small meals each day instead of 3 large meals
- Keep snacks nearby for when you feel like eating
- Add extra protein and calories to your diet

Tell your healthcare provider right away about any side effects you experience.

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Additional serious side effects to watch out for

Tell your healthcare provider right away if you have any of these symptoms:

Lung or breathing problems

- Trouble breathing or shortness of breath
- Cough
- Fever

Liver problems

- 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

Increased risk of tear (perforation) in stomach or intestine if you:

- Take certain medicines with GILOTRIF, including corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs)
- Have a history of stomach or intestinal ulcers, or diverticular disease (inflammation in parts of large intestine)
- Have severe stomach-area (abdomen) pain during treatment with GILOTRIF

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Eye problems

- Eye pain, swelling, redness, or tearing
- Blurred vision
- Sensitivity to light
- Other changes in your vision

Heart problems

- 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

These are not all of the possible side effects of GILOTRIF. For more information, ask your healthcare provider or pharmacist. **Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

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Check in with your healthcare provider often, especially during the first 2 weeks after starting treatment

Your healthcare provider will schedule regular checkups to see how you are doing. You will also have regular tests that tell your healthcare provider how your cancer is responding to GILOTRIF. Depending on how you are doing, your healthcare provider will update your treatment plan as needed.

Talk to your healthcare provider

- If you feel uncomfortable or side effects become more serious or affect your daily activities; call your healthcare provider right away, even if it's before your appointment
- Track your condition by keeping a diary. This makes it easier to report back to your healthcare provider. You might want to use the "My Diary" included in your "My Support Kit" for this

Remember, always take GILOTRIF exactly as your healthcare provider instructed. Do not change the dose or stop taking GILOTRIF unless told to do so by your healthcare provider.

TELL YOUR HEALTHCARE PROVIDER ABOUT SIDE EFFECTS RIGHT AWAY

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GILOTRIF Patient Services

Nurse & Pharmacist support program

Participating patients will receive:

- Phone calls from dedicated oncology-trained nurses and pharmacists at your convenience, to help as you start your first weeks on GILOTRIF
- Up to 5 phone calls at critical points of time during your GILOTRIF treatment
- Tips to help you manage treatment-related adverse reactions

Pharmacy support

Our Accredo® concierge pharmacy team is available from 8:30am to 7pm ET to answer questions related to GILOTRIF.

To speak to a member of our dedicated Accredo® team for Pharmacy Support or more information about the Patient Services programs below, call: 1-844-569-2836.

GILOTRIF Dose Exchange™

Makes it easy to switch to a new dose, eliminating an additional GILOTRIF co-pay in a given month for eligible patients serviced through Accredo®.

Coverage and reimbursement assistance

Our Reimbursement Specialists personally work with you to resolve any issues you may have with benefit verification, prior authorization, or denials and appeal of claims.

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Co-pay Assistance Program

- If you have commercial insurance, you will have the opportunity to enroll into the GILOTRIF co-pay program
- If you are covered by any form of government-funded healthcare programs (Medicare, Medicaid, Tricare, VA, etc), you are not eligible for the program. Also, if you are paying cash, you will not be eligible
- You may receive GILOTRIF for as little as \$0 per month. There is no card to carry or worry about
- Please call **1-877-546-5349** for additional information
- Please see full [terms and conditions](#)

Alternative funding support

Get connected to charitable foundations that may be able to help you offset the cost of your co-pays, co-insurance, or other treatment-related expenses if you are insured by a Medicare plan.

GILOTRIF Bridge

If you experience a payer delay (delay of coverage approval) by your prescription insurance carrier of more than 5 days for the FDA approved use of GILOTRIF, you may be eligible to receive a one-time free 15 days supply of GILOTRIF. This program allows eligible patients to start therapy and avoid prolonged payer delays.*

*For commercial and Medicare Part D insured people treated with GILOTRIF who may experience a payer delay ≥ 5 days for the FDA-approved indication, or when a change in insurance and a treatment gap is expected.

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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.

IMPORTANT SAFETY INFORMATION FOR GILOTRIF[®] (afatinib) TABLETS

Before you take GILOTRIF, tell your healthcare provider 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

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- have a history of severe dry eye or any other eye problems. Tell your healthcare provider if you wear contact lenses.
- have heart problems
- have any other medical conditions
- 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 healthcare provider about birth control methods that may be right for you.
 - Tell your healthcare provider 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 while taking GILOTRIF and for 2 weeks after your last dose of GILOTRIF. Talk to your healthcare provider about the best way to feed your baby if you take GILOTRIF.

Tell your healthcare provider 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.

What to 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.

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IMPORTANT SAFETY INFORMATION FOR GILOTRIF® (afatinib) TABLETS (cont'd)

GILOTRIF may cause serious side effects, including:

- **Diarrhea.** Diarrhea is common with GILOTRIF and may sometimes be severe. Severe diarrhea can cause loss of body fluid (dehydration) and kidney problems that can sometimes lead to death. During your treatment with GILOTRIF, your healthcare provider should prescribe medicines to treat diarrhea. Take this medicine exactly as your healthcare provider tells you to. Tell your healthcare provider 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 healthcare provider 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 healthcare provider 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 healthcare provider 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 healthcare provider will do blood tests to check your liver function during your treatment with GILOTRIF.

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IMPORTANT SAFETY INFORMATION FOR GILOTRIF® (afatinib) TABLETS (cont'd)

- **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 healthcare provider right away if you have symptoms of eye problems. Symptoms may include:
 - eye pain, swelling, redness, or tearing
 - blurred vision
 - sensitivity to light
 - other changes in your vision
- **Heart problems.** Tell your healthcare provider right away if you have any 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 healthcare provider may change your dose, temporarily stop or permanently stop treatment with GILOTRIF if you have certain side effects.

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IMPORTANT SAFETY INFORMATION FOR GILOTRIF® (afatinib) TABLETS (cont'd)

The most common side effects of GILOTRIF include diarrhea, rash, acne, mouth sores, nail inflammation, dry skin, decreased appetite, nausea, vomiting, and itching.

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

Tell your healthcare provider 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 healthcare provider or pharmacist.

Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Things to remember when taking GILOTRIF

Tell your healthcare provider about side effects right away, and talk to your healthcare provider about any change in your health—even if it seems unrelated to lung cancer. Many organizations provide authoritative, helpful information. Ask your healthcare provider about these resources.



GILOTRIF is a once-daily oral tablet. Take GILOTRIF exactly how your healthcare provider tells you to take it.



Take GILOTRIF on an empty stomach.



After taking GILOTRIF, wait at least 1 hour before eating.



Don't take 2 doses of GILOTRIF at the same time.

FOR MORE INFORMATION, VISIT [GILOTRIF.COM](https://gilotrif.com)

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