







### **AFATINIB**

### Name of your medication

Generic name — afatinib (ay-FA-tih-nib) Brand name — Gilotrif® (JEE-loh-trif)

#### Common uses

Dose and schedule

Afatinib is used to treat people with non-small cell lung cancer (NSCLC) with an epidermal growth factor receptor (EGFR) genetic mutation or a squamous cell type of NSCLC.

Afatinib may also be used for other treatments.

Taking afatinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of afatinib is 40 milligrams (40 mg) to be taken by mouth once daily. The dose may be adjusted by your care provider based on your individual needs.
- Afatinib must be taken on an empty stomach (at least one hour before or two hours after a meal or snack) at the same time each day.
- Afatinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow afatinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of afatinib:
  - Only take the missed dose if it has been less than 12 hours since you were supposed to take it. Then, take the next dose at the regularly scheduled time.
  - Do not take two doses at one time.
  - Be sure to write down if you miss a dose and let your care team know about any missed doses.

#### **Drug and food interactions**

- Afatinib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- ☐ Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

#### Storage and handling

Handle afatinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- ☐ Store afatinib at room temperature (68°F–77°F) in a dry location away from light.
- ☐ Keep afatinib out of reach of children and pets.









### **AFATINIB**

- Leave afatinib in the provided packaging until it is ready to be taken.
- Whenever possible, give afatinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give afatinib to you, they also need to follow these steps:
  - 1. Wash hands with soap and water.
  - 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
  - 3. Gently transfer the afatinib from its package to a small medicine or other disposable cup.
  - 4. Administer the medicine immediately by mouth with water.
  - 5. Remove gloves and do not use them for anything else.
  - 6. Throw gloves and medicine cup in household trash.
  - 7. Wash hands with soap and water.
- ☐ If a daily pill box or pill reminder will be used, contact your care team before using:
  - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
  - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
- If you have any unused afatinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of afatinib.
- If you are traveling, put your afatinib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.









### **AFATINIB**

#### **Side Effects of Afatinib**

Below are common side effects that have been known to happen in about one third or more of patients taking afatinib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management	
Diarrhea (loose and/ or urgent bowel movements)	<ul> <li>Monitor how many bowel movements you have each day.</li> <li>Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake related to some other health problem.</li> <li>Eat small, frequent meals throughout the day rather than a few large meals.</li> <li>Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast).</li> <li>Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains.</li> <li>Avoid foods that cause gas, such as broccoli and beans.</li> <li>Avoid lactose-containing foods, such as yogurt and milk.</li> <li>Avoid spicy, fried, and greasy foods.</li> </ul> Contact your provider if any of the following occur: <ul> <li>The number of bowel movements you have in a day increases by four or more.</li> <li>You feel dizzy or lightheaded.</li> </ul>	
	Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.	
Acne-like rash	<ul> <li>A rash that looks like acne may appear on your face, chest, and upper back while taking this medication.</li> <li>Your doctor may prescribe medication to help prevent or manage the rash.</li> <li>If you get a rash, keep the area around it clean and dry.</li> <li>Check with your care provider before using anything to treat it.</li> <li>Do not use over-the-counter acne treatments, such as benzoyl peroxide or salicylic acid, and soaps containing alcohol.</li> <li>Oatmeal baths and unscented moisturizers may help with itching.</li> <li>Sunlight can make symptoms worse.</li> <li>Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs from 10 am-4 pm.</li> <li>Wear long-sleeved clothing, with UV protection if possible.</li> <li>Wear broad-brimmed hats.</li> <li>Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle.</li> </ul>	
	Use lip balm with at least SPF 30.	

Continued on the next page









### AFATINIB

Mouth irritation or sores	<ul> <li>Practice good mouth care.</li> <li>Rinse your mouth frequently.</li> <li>Brush your teeth with a soft toothbrush or cotton swab after meals.</li> <li>Use a mild nonalcohol mouth rinse at least four times a day (after eating and at bedtime). For example, you can use a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water.</li> <li>If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol.</li> </ul>
	Call your care provider if you experience pain or sores in your mouth or throat.
Nail changes	<ul> <li>Usually changes start at the cuticle and may affect the skin around the nail.</li> <li>Biting, chewing, or picking at your nails can increase the risk for infection.</li> <li>Talk to your care provider if you notice any changes in your nails.</li> </ul>
Changes in liver function	Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:  • Yellowing of the skin or whites of your eyes  • Dark or brown urine  • Unusual bleeding or bruising
Changes in kidney function	Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice either of the following:  Decreased amount of urination  Unusual swelling in your legs and feet
	<ul> <li>Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose fitting clothing.</li> <li>Avoid using perfumes and cologne as these products may increase rash symptoms.</li> <li>Avoid being in the heat for long periods of time.</li> <li>Your provider may recommend an over-the-counter antihistamine or a topical cream.</li> </ul>
Rash or itchy skin	<ul> <li>Sunlight can make symptoms worse.</li> <li>Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs from 10 am-4 pm.</li> <li>Wear long-sleeved clothing, with UV protection if possible.</li> <li>Wear broad-brimmed hats.</li> <li>Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle.</li> </ul>
	If your rash or itching continues to worsen, contact your care provider.









### **AFATINIB**

Possible Side Effect	Management
Changes in electrolytes and other laboratory values  • Low potassium levels	<ul> <li>Changes in some lab values may occur and will be monitored by a simple blood test.</li> <li>You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem.</li> <li>More severe changes may occur, which can be a sign of a serious problem.</li> <li>Notify your care provider if you have any of the following:</li> <li>Shortness of breath</li> <li>Chest discomfort</li> <li>Weakness or fatigue</li> <li>New aches and pains</li> <li>Headaches</li> <li>Dizziness</li> <li>Swelling of your legs or feet</li> <li>Red- or brown-colored urine</li> </ul>

#### Serious side effects of afatinib

- Afatinib may be harmful to your lungs. Inform your care provider of any new difficulty breathing, cough, or fever. Your provider may stop treatment with afatinib if your lungs are affected.
- Afatinib may be harmful to your eyes. Be sure to inform your care provider of any issue you have with your vision, or pain in your eyes. Your provider may stop treatment with afatinib if your eyes are affected.
- Rarely, afatanib can cause severe skin reactions, including Stevens-Johnson syndrome, which can be life-threatening.
- Afatanib may rarely cause a tear or hole in your intestine, called bowel perforation. Speak to your care team right away if you have a high fever, or nausea, vomiting, or severe stomach pain.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

\_ (INSTITUTIONAL CONTACT INFO)

### Handling body fluids and waste

Afatinib remains in your body for several days after it is taken, so some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take afatinib, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
  - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid
    and flush twice to ensure all waste has been discarded.
  - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
  - Wash hands with soap and water after using the toilet.









### **AFATINIB**

If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan wit
soap and water every day.

- ☐ If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- ☐ Wash any skin that has been exposed to body waste or afatinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- ☐ Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

### Pregnancy, sexual activity, and contraception

- □ Women should not become pregnant and men should not get a partner pregnant while taking afatinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 2 weeks after the last dose of afatinib.
- ☐ Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- □ Do not breastfeed while taking afatinib and for 2 weeks after the last dose of afatinib.
- Inform your care provider if you become pregnant.
- ☐ It is safe to hug and kiss. Special precautions may be needed for sexual activity while on afatinib, and you are encouraged to ask your care provider.

#### **Obtaining medication**

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	(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)









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#### **Additional resources**

Product website: http://www.gilotrif.com

Product prescribing information: https://content.boehringer-ingelheim.com/DAM/07c11f94-358a-439d-b0c8-

af1e011f04c4/gilotrif-us-pi.pdf

Product resources: https://content.boehringer-ingelheim.com/DAM/98f3a99a-0189-4f0f-a665-af1e011f1358/

gilotrif-us-ppi.pdf

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Additional instructions			

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