

ORAL CANCER TREATMENT EDUCATION



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GEFITINIB

Name of your medication

Generic name — gefitinib (geh-FIH-tih-nib)
Brand name — Iressa® (i-REH-suh)

Common uses

Gefitinib is used to treat adults with metastatic non-small cell lung cancer (NSCLC) that has a genetic mutation called epidermal growth factor receptor (EGFR).

Gefitinib may also be used for other treatments.

Dose and schedule

Taking gefitinib 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 gefitinib is 250 milligrams (250 mg) to be taken by mouth at a scheduled time once a day.
- Gefitinib can be taken with or without food at the same time each day.
- Gefitinib should be taken whole and not crushed or cut. If you are unable to swallow gefitinib, dissolve gefitinib tablet in 4 to 8 ounces of water by dropping the tablet in water, and stir for approximately 15 minutes. Immediately drink the liquid or administer through a naso-gastric tube. Rinse the container with 4 to 8 ounces of water and immediately drink. Talk to your care provider or pharmacist for other possible options.
- If you miss a dose of gefitinib:
 - 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 the missed dose if it has been more than 12 hours since you should have taken it. Simply take your 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 notify your care provider about any missed doses.

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GEFITINIB

Storage and handling

Handle gefitinib 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 gefitinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep gefitinib out of reach of children and pets.
- Leave gefitinib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give gefitinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the gefitinib 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 gefitinib 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 is used, a separate one should be used for gefitinib. **Do not** mix other medications into the box with gefitinib. 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 gefitinib, **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 gefitinib.
- If you are traveling, put your gefitinib in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

ORAL CANCER TREATMENT EDUCATION



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GEFITINIB

Handling body fluids and waste

Gefitinib 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 gefitinib, 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.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with 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 gefitinib 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.

Drug and food interactions

- Gefitinib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with gefitinib, so avoid eating or drinking these during treatment with gefitinib.
- Talk with your care provider or pharmacist before taking new medications or supplements or receiving any vaccines.

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GEFITINIB

Side Effects of Gefitinib

The common side effects that have been known to happen in more than 30% of patients taking gefitinib are listed in 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
Acne-like rash	<p>A rash that looks like acne may develop on your face, chest, and upper back while taking this medication.</p> <ul style="list-style-type: none"> Your doctor may prescribe medication to help prevent or manage the rash. If you do get a rash, keep the surrounding area clean and dry. Check with your care provider before using anything to treat the rash. Do not use over-the-counter acne treatments, such as benzoyl peroxide or salicylic acid, or soaps containing alcohol. Oatmeal baths and unscented moisturizers may help with itching. Sunlight can make symptoms worse. <ul style="list-style-type: none"> Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultraviolet) radiation occurs from the hours of 10 am through 4 pm. Wear long-sleeved clothing with UV protection, if possible. Wear broad-brimmed hats. Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. Use lip balm with at least SPF 30
Changes in liver function	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> Yellowing of the skin or whites of your eyes Dark or brown urine Bleeding or bruising
Diarrhea	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> Drink 8–10 glasses of water/fluid each day unless your care provider has instructed you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. Avoid foods that cause gas, such as broccoli and beans. Avoid lactose-containing foods, such as yogurt and milk. Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> The number of bowel movements you have in a day increases by 4 or more. You feel dizzy or lightheaded. <p>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.</p>

Continued on the next page

ORAL CANCER TREATMENT EDUCATION



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Possible Side Effect

Management

Kidney damage

Your care provider will monitor your kidney function by checking the amount of protein in your urine.

Serious side effects

- Gefitinib may cause your lung tissue to scar, which is called interstitial lung disease. Call your care team if you are feeling short of breath, have a fever, or have a lasting dry cough.
- Gefitinib may be harmful to your liver. Seek medical attention if you notice yellowing of the skin or whites of your eyes, dark or brown urine, bleeding, or bruising.
- Gefitinib 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.
- Gefitinib may be harmful to your eyes. Call your care team if you have any issue with your vision, or if you have pain in your eyes.
- Rarely, gefitinib can cause severe skin reactions, including Stevens–Johnson syndrome, which can be life threatening. Seek emergency care if you have a severe rash or a rash on your mouth, eyes, or genitals.

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

_____ (INSTITUTIONAL CONTACT INFO)

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking gefitinib. 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 gefitinib.
- Do not breastfeed while taking gefitinib and for 2 weeks after the last dose of gefitinib.
- Inform your care provider if you become pregnant.
- It is safe to hug and kiss, but special precautions may be needed for sexual activity while on oral chemotherapy. You are encouraged to talk to your care provider.

Obtaining medication

- Talk with your care provider about how to obtain your gefitinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

ORAL CANCER TREATMENT EDUCATION



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Additional resources

Product website: www.iressa-usa.com

Product prescribing information: www.accessdata.fda.gov/drugsatfda_docs/label/2015/206995s000lbl.pdf

Product resources: www.iressa-usa.com/lung-cancer-support/nsclc-resources.html

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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