

ORAL CHEMOTHERAPY EDUCATION



FEDRATINIB

Name of your medication

Generic name — fedratinib (fed-RA-ti-nib)
Brand name — Inrebic® (inn-REH-bik)

Approved uses

Fedratinib is used to treat myelofibrosis.

Dose and schedule

Taking fedratinib 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 fedratinib is 400 milligrams (400 mg) to be taken by mouth at a scheduled time once a day.
- Fedratinib can be taken with or without food, but at the same time each day.
- Fedratinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow fedratinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of fedratinib, do not take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time. Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- Fedratinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with fedratinib; avoid eating or drinking this during treatment with fedratinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle fedratinib 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 fedratinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep fedratinib out of reach of children and pets.
- Leave fedratinib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give fedratinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the fedratinib 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 fedratinib from its package to a small medicine or other disposable cup.

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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, contact your care provider 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.

Side Effects of Fedratinib

Below are common side effects that have been known to happen in about one-third or more of patients taking fedratinib; these 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
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none">• Try to get 7–8 hours of sleep per night.• Avoid operating heavy machinery if you feel too tired.• Find a balance between work and rest.• Stay as active as possible, but know that it is okay to rest as needed.• You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none">• Shortness of breath• Dizziness• Palpitations

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Possible Side Effect	Management
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or 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 either of the following occurs:</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>
<p>Changes in kidney function</p>	<p>Your kidney (renal) 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"> • Decreased amount of urination • Unusual swelling in your legs and feet
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently, and do not pick your nose. • Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, notice blood in your urine or stool, cough up blood, or have prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>

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Possible Side Effect	Management
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
Nausea or vomiting	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or 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 foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication that can help with the nausea or vomiting.</p>
Changes in electrolytes and other laboratory values <ul style="list-style-type: none"> • High pancreas enzyme levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs and feet • Red- or brown-colored urine

Serious side effects

- ☐ Fedratinib may cause a serious and sometimes fatal brain problem called encephalopathy (including Wernicke encephalopathy). Wernicke encephalopathy is a medical emergency and can happen if you do not have enough vitamin B1 (thiamine) in your body. Your care team will do a blood test to check your vitamin B1 levels before starting and during treatment with fedratinib.

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

(INSTITUTIONAL CONTACT INFO)

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Handling body fluids and waste

Since fedratinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take fedratinib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to 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 that 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 fedratinib 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

- There are no scientific data on the safety of fedratinib during pregnancy. Discuss with your healthcare team before using fedratinib if you plan to become pregnant or get a partner pregnant, or if you are pregnant or breastfeeding.
- Please 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 oral chemotherapy, and you are encouraged to ask your care team for assistance.

Obtaining medication

- Talk with your care provider about the process for obtaining your fedratinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product prescribing information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212327s000lbl.pdf

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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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