Fedratinib

Patient Education Sheets
Understanding Your Cancer Treatment

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for a type of blood cancer called myelofibrosis (MF).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Fedratinib (feh-DRAH-tih-nib): Inrebic (in-REH-bik)	Slows down or stops the growth of cancer cells by blocking specific proteins that helps them survive.	Capsule(s) taken by mouth.

Treatment Administration and Schedule

Your fedratinib dosing instructions:

_____

_____

_____

- Fedratinib comes in 1 capsule strength: 100 mg.
- Your dose might differ, but fedratinib is typically taken as four 100 mg capsules (400 mg total dose) by mouth once daily.
- Take fedratinib 1 time each day, around the same time each day.
- Take fedratinib with or without food. Taking fedratinib with a high fat meal may help to reduce nausea and vomiting symptoms.
- If you cannot swallow fedratinib capsules whole or have a nasogastric tube, the capsules can be opened, and the contents can be mixed with Ensure® Plus liquid nutritional supplement:
    - Carefully open your prescribed dose of fedratinib capsules into a glass container and mix it with about 180 mL (6 oz) of liquid nutritional supplement at room temperature, between 68°F to 77°F (20°C to 25°C).
    - Swallow the mixture right away or give it through a nasogastric (NG) tube (French size 14 or 16) within 2 hours of preparation. If using a NG tube, flush the NG tube with 60 mL (2 oz) of water after giving the fedratinib mixture.
    - Throw away prepared dose if not given within 2 hours and mix a new dose.

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Treatment Administration and Schedule Continued

- Do not change your dose or stop taking fedratinib unless your care team tells you to. If you stop treatment with fedratinib, symptoms of your condition may return.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking fedratinib if you develop certain side effects.
- If you vomit or miss a dose of fedratinib, skip the missed dose and take your usual dose the next day at your regularly scheduled time. Do not take 2 doses to make up for the missed dose.
- If you take too much fedratinib, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Fedratinib

- Store fedratinib below 86°F (30°C).
- Keep fedratinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused fedratinib.

Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To prevent low Vitamin B1 levels	
To help prevent or treat nausea and vomiting	
Other	

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Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Platelet Count (Thrombocytopenia)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. Talk to your care team if you have: • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Sudden or severe headache • Blood in your urine or stool • Blood in your spit after coughing
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak, very tired, or look pale. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

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<table>
<tr><td>Nausea and Vomiting</td><td>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.

Recommendations:
Eat smaller, more frequent meals.
Avoid fatty, fried, spicy, or highly sweet foods.
Eat bland foods at room temperature and drink clear liquids.
If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods.
Your care team may prescribe medicine for these symptoms.
Talk to your care team if you have:
Vomiting for more than 24 hours
Nonstop vomiting
Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)
Blood or coffee-ground-like appearance in your vomit
Severe stomach pain that does not go away after vomiting</td></tr>
<tr><td>Liver Problems</td><td>Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment.

Talk to your care team if you have:
Yellowing of your skin or the white part of your eyes (jaundice)
Severe nausea or vomiting
Pain on the right side of your stomach area (abdomen)
Dark, tea-colored urine
Bleeding or bruising more easily than normal</td></tr>
<tr><td>Diarrhea</td><td>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.

Recommendations:
Keep track of how often you go to the bathroom each day.
Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise.
Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast).
If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods.
Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium).
Talk to your care team if you have:
4 or more bowel movements than normal in 24 hours
Dizziness or lightheadedness while having diarrhea
Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)
Bloody diarrhea</td></tr>
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Kidney Problems	Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment. Recommendations: • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. Talk to your care team if you have: • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
High Amylase and Lipase Levels in Your Blood	Description: Treatment may cause high levels of amylase and lipase in your blood. This may indicate a problem with your pancreas. Your care team will do blood tests to check you for these changes and will treat you if needed. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Fast heartbeat • Severe stomach-area (abdominal) pain that radiates to the back • Worsening pain after eating • Severe nausea or vomiting • Diarrhea • Yellowing of your skin or the white part of your eyes (jaundice)

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Encephalopathy (Including Wernicke's Encephalopathy) (Boxed Warning)	A serious neurological problem called encephalopathy (including Wernicke's encephalopathy) has happened in some people who take fedratinib. Wernicke's encephalopathy is a neurologic emergency that 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 level and treat you with Vitamin B1 if your level is too low before starting treatment with fedratinib. Your care team may also check your Vitamin B1 level during treatment with fedratinib. You should take a Vitamin B1 supplement daily during treatment with fedratinib. Get emergency medical help right away if you develop: • Confusion, memory problems, or drowsiness • Problems with balance and movement, such as difficulty walking • Eye problems, such as double or blurred vision or abnormal eye movements Call your care team right away if you have: • Diarrhea • Nausea • Vomiting • Weight loss that does not get better with treatment
Blood Clots or Blockage (Thrombosis) in Your Blood Vessels (Arteries and Veins)	Increased risk of blood clots in the veins of the legs (deep vein thrombosis (DVT)) or lungs (pulmonary embolism (PE)) have happened in people taking another JAK-inhibitor for rheumatoid arthritis and may be life-threatening. • Chest or upper back pain or pressure • Swelling or pain in your legs, arms, back, neck, or jaw • Shortness of breath or difficulty breathing • Numbness or weakness on one side of your body • Trouble talking • Headache • Vision changes
Major Cardiac Events, Such As Heart Attack or Stroke	An increased risk of major cardiac events has happened in people, especially those who have cardiovascular risk factors and who are current or past smokers, while taking another Janus Kinase (JAK)-inhibitor to treat rheumatoid arthritis. Get emergency help right away if you get any symptoms of a heart attack or stroke during treatment with fedratinib, including: • Discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back • Severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw • Pain or discomfort in your arms, back, neck, jaw, or stomach • Shortness of breath with or without chest discomfort • Breaking out in a cold sweat • Nausea or vomiting • Feeling lightheaded • Weakness in one part or on one side of your body • Slurred speech

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Eye Problems (Uveitis)	Fedratinib may cause inflammation of the middle layer of the eyeball (uvea) called uveitis. You may need to see an eye specialist to check your eyes if you develop any signs and symptoms of eye problems. • Eye pain • Redness of the eye • Sensitivity to light • New or increased floaters (specks or threads that float in your vision) • Decrease in your vision
Risk of New Cancers	There is a risk of developing new cancers during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms of new cancers.

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- It is **not known** if treatment may **harm an unborn baby**.
    - If you are able to become pregnant:
        - Take a pregnancy test before starting treatment.
        - Use an effective method of birth control during treatment with fedratinib.
        - If you think you might be pregnant or if you become pregnant, tell your care team right away.
    - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment with fedratinib.
- **Do NOT breastfeed** during treatment and for 1 month after your last dose of fedratinib. Talk to your care team about the best way to feed your baby during treatment with fedratinib.

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Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **Signs and symptoms of myelofibrosis may worsen after you stop treatment with fedratinib**. Do not interrupt or stop treatment with fedratinib without talking to your care team. If you need to stop treatment with fedratinib, your care team may give you instructions for slowly stopping treatment. Tell your care team right away if you get any of the following signs and symptoms after stopping treatment with fedratinib:
  - Fever
  - Trouble breathing
  - Feeling dizzy or lightheaded
  - Weakness
  - Night sweats
  - Pain in your left upper stomach (abdomen) area or left shoulder
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.

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