

Fedratinib (Inrebic)

About This Medicine

FEDRATINIB (fe dra TIN ib) treats bone marrow cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

Possible Side Effects

- Decrease in red blood cells. This may make you feel more tired.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)

Note: Each of the side effects above was reported in 20% or greater of people treated with fedratinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Changes in your liver and pancreas function
- Severe nausea, vomiting and diarrhea
- Severe decrease in red blood cells and platelets which may make you tired and weak and raise your risk of bleeding.
- Changes in your central nervous system such as Wernicke's encephalopathy can happen, which can be life-threatening. Wernicke's encephalopathy is a condition that can be caused by a lack of thiamine (vitamin B1) because of alcoholism, poor nutrition, some medicines, and other medical conditions. Your care team will monitor your thiamine levels. You could feel extreme tiredness, agitation, confusion, difficulty walking or problems with balance, trouble with memory, have hallucinations (see or hear things that are not there), trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, numbness or lack of strength to your arms, legs, face, or body, seizures or coma. **If you start to have any of these symptoms let your care team know right away.**

- The use of this type of medicine, a JAK inhibitor, for the treatment of rheumatoid arthritis, has been shown to raise the risk of getting a second cancer such as lymphoma and other cancers. This risk is increased in people who currently smoke or have smoked in the past.
- Life-threatening blood clots and events such as stroke and heart attack have happened in people taking this type of medicine, a JAK inhibitor, for the treatment of rheumatoid arthritis. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain. These risks are increased in people who have risk factors for heart problems and/or who currently smoke or have smoked in the past.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

How to Take Your Medicine

- Swallow the medicine whole with or without food. If you have nausea, taking fedratinib with a high fat meal may help with nausea and vomiting.
- It is important for you to take thiamine daily according to your care team's direction.
- **Missed dose:** If you miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container below 86°F. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.



- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop diarrhea.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with fedratinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms

- Fever of 100.4° F (38° C) or higher
- Chills
- Feeling dizzy or lightheaded
- Tiredness that interferes with your daily activities
- Easy bleeding or bruising
- Blurry vision or changes in your eyesight
- Extreme tiredness, agitation, or confusion
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Hallucinations
- Trouble understanding or speaking
- Loss of control of bowels or bladder
- Numbness or lack of strength to your arms, legs, face, or body
- Your leg is swollen, red, warm and/or painful
- Wheezing and/or trouble breathing

- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Severe pain in your abdomen that may spread to your back
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin

Reproduction Warnings

- **Pregnancy warning:** Talk with your care team if you are pregnant or planning to become pregnant while taking this medicine. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for at least 1 month after the last dose.

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