

PATIENT & CAREGIVER EDUCATION Fedratinib

This information from Lexicomp[®] explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Inrebic

Brand Names: Canada

Inrebic

Warning

- Severe brain or nervous system problems, like Wernicke's encephalopathy, have happened with this drug. Sometimes, this has been deadly. Talk with your doctor if you have low thiamine (vitamin B1) levels, poor nutrition, diarrhea, upset stomach, or throwing up. Call your doctor right away if you feel confused or very sleepy. Call your doctor right away if you have a change in balance, change in eyesight, trouble thinking or walking, or memory problems.
- Have your thiamine level checked as you have been told by your doctor. Low thiamine levels will need to be treated before starting this drug.
- Take a thiamine supplement as you have been told by your doctor.

What is this drug used for?

• It is used to treat myelofibrosis.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have liver disease.
- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, seizures, and others. There are many drugs that must not be taken with this drug.
- If you are breast-feeding. Do not breast-feed while you take this drug or for 1 month after your last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- A drug (tofacitinib) like this one has been shown to raise the risk of heart attack, stroke, blood clots, some types of cancer, and death. These effects were seen in a study of people taking tofacitinib to treat rheumatoid arthritis. These people were at least 50 years of age and also had at least 1 heart disease risk factor. It is not known if the raised risk happens with this drug. This drug is not approved to treat rheumatoid arthritis. Call your doctor right away if you have signs of a heart attack, stroke, or blood clot like chest, throat, neck, or jaw tightness, pain, pressure, or heaviness; abnormal arm, back, neck, jaw, or stomach pain; coughing up blood; shortness of breath; cold sweats; severe upset stomach or throwing up; swelling, warmth, numbness, coldness, color change, or pain in a leg or arm; trouble speaking, swallowing, or thinking; weakness on 1 side of the body; change in balance; drooping on one side

of the face; feeling lightheaded; or change in eyesight. Call your doctor right away if you have signs of certain types of cancer like a skin lump or growth; change in color or size of a mole; or swollen gland, night sweats, shortness of breath, or weight loss without trying.

- Tell your doctor if you smoke, have smoked in the past, or have ever had a heart attack, other heart problems, stroke, or blood clot.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Signs of low sodium levels like headache, trouble focusing, memory problems, feeling confused, weakness, seizures, or change in balance.
- Low blood cell counts have happened with this drug. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. Call your doctor right away if you have signs of infection like fever, chills, or sore throat; any unexplained bruising or bleeding; or if you feel very tired or weak.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Feeling dizzy, tired, or weak.
- Muscle spasm.
- Pain in arms or legs.
- Headache.
- Weight gain.
- Bone pain.
- Constipation, diarrhea, throwing up, and upset stomach are common with this drug. If these happen, talk with your doctor about ways to lower these side effects. Call your doctor right away if any of these effects bother you, do not go away, or are severe.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Taking this drug with a high-fat meal may help if you have upset stomach and throwing up.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

What do I do if I miss a dose?

- Skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush

down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away.
 Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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