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(For additional information [see "Tofacitinib: Drug information"](#) and [see "Tofacitinib: Pediatric drug information"](#))

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Xeljanz; Xeljanz XR

Brand Names: Canada

Xeljanz; Xeljanz XR

Warning

- Severe infections like tuberculosis, shingles, fungal infections and other bacterial or viral infections have happened in patients who take this drug. Sometimes, these have been deadly. The risk is greater if you also take drugs that suppress the immune system like methotrexate or corticosteroids. If you get a bad infection, your doctor may stop this drug until the infection is under control. Call your doctor right away if you have fever, chills, or sweating; cough; muscle aches; shortness of breath; more sputum or change in color of sputum; red, warm, swollen, painful, or blistered skin; weight loss; stomach pain; diarrhea; pain with passing urine or passing urine more often; or feeling tired or weak.
- TB (tuberculosis) has been seen in patients started on this drug. These patients were exposed to TB in the past, but never got the infection. You will be tested to see if you have been exposed to TB before starting this drug.
- A greater risk of death was seen in some people who took higher than recommended doses of this drug for rheumatoid arthritis. These people were

50 years of age and older. They also had at least 1 heart disease risk factor. Tell your doctor if you have ever had heart problems.

- Blood clots have happened with this drug. A raised risk of blood clots was seen in a study in people with rheumatoid arthritis who were taking a higher than recommended dose. These people were 50 years of age or older and also had at least 1 heart disease risk factor. Rarely, blood clots in the lungs have also happened in people with ulcerative colitis. Sometimes, blood clots have been deadly. Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, coldness, change of color, 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; or change in eyesight.
- Lymphoma, skin cancer, and other types of cancer have happened in people treated with this drug.
- If you have had a kidney transplant and take drugs that work on the immune system, you are at a greater risk for a problem with certain white blood cells growing out of control called post-transplant lymphoproliferative disorder caused by the Epstein Barr virus. Talk with your doctor.

What is this drug used for?

- It is used to treat some types of arthritis.
- It is used to treat ulcerative colitis.
- It may be given to you for other reasons. Talk with the doctor.

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 any of these health problems: Kidney disease or liver disease.
- If you have anemia.

- If you have an infection or a low white blood cell count.
- If you are taking rifampin.
- If you are taking any of these drugs: Abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, rituximab, secukinumab, tocilizumab, ustekinumab, or vedolizumab.
- If you are taking any drugs used to suppress your immune system like azathioprine or cyclosporine. There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.
- If you are breast-feeding. Do not breast-feed while you take this drug. You will also need to avoid breast-feeding after you stop this drug until there is no more of this drug in your body. Talk with your doctor to see how long you need to avoid breast-feeding after you stop this drug.

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?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Some viral infections like herpes zoster have become active again with this drug. Tell your doctor if you have ever had a viral infection like herpes zoster. Talk with your doctor.
- Hepatitis B or C testing may be done. A hepatitis B or C infection may get worse while taking this drug.
- Have blood work checked as you have been told by the doctor. Talk with the

doctor.

- High cholesterol has happened with this drug. If you have questions, talk with the doctor.
- You may need to have your skin checked while you take this drug. Talk with your doctor.
- If you drink grapefruit juice or eat grapefruit often, talk with your doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- Make sure you are up to date with all your vaccines before treatment with this drug.
- Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- If you have high blood sugar (diabetes), talk with your doctor. You may be more likely to get infections.
- This drug may be used with other drugs to treat your health condition. If you are also taking other drugs, talk with your doctor about the risks and side effects that may happen.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may cause fertility problems. This may affect being able to have children. It is not known if this will go back to normal. If you have questions, talk with the doctor.
- 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.

Extended-release tablets:

- You may see the tablet shell in your stool. This is normal and not a cause for concern.

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, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Warm, red, or painful skin or sores on the body.
- Shingles.
- Change in color or size of a mole.
- A skin lump or growth.
- Feeling very tired or weak.
- Change in bowel habits.
- Muscle pain or weakness.
- Slow heartbeat.
- A heartbeat that does not feel normal.
- Call your doctor right away if you have a swollen gland, night sweats, shortness of breath, or weight loss without trying.
- Tears in the stomach or bowel wall have happened in certain people taking this drug. Call your doctor right away if you have swelling or pain in your stomach

that is very bad, gets worse, or does not go away. Call your doctor right away if you throw up blood or have throw up that looks like coffee grounds; upset stomach or throwing up that does not go away; or black, tarry, or bloody stools.

- Some people have had lung problems with this drug. Sometimes, this has been deadly. Call your doctor right away if you have signs of lung problems like shortness of breath or other trouble breathing, cough that is new or worse, or fever.

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:

- Headache.
- Diarrhea.
- Signs of a common cold.
- Nose or throat irritation.
- Upset stomach or throwing up.

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.

How is this drug best taken?

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

All products:

- Take with or without food.
- Keep taking this drug as you have been told by your doctor or other health care

provider, even if you feel well.

- Do not take more than what your doctor told you to take. Taking more than you are told may raise your chance of very bad side effects.
- If you are on dialysis and are taking this drug on the day you get dialysis, take it after your dialysis. If you have questions, talk with your doctor.

Extended-release tablets:

- Swallow whole. Do not chew, break, or crush.

Oral solution:

- If the adapter has not been put in the bottle when you get it, follow how to prepare the bottle as you have been told or read the package insert.
- Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.

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?

All products:

- 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.

All tablet products:

- Store in original container.

Oral solution:

- Store in the original container to protect from light.
- After opening, throw away any part not used after 60 days.

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.
- 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.

Last Reviewed Date

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you

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