

PATIENT & CAREGIVER EDUCATION

Upadacitinib

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

Rinvoq; Rinvoq LQ

Brand Names: Canada

Rinvoq

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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.
- Lymphoma and other cancers have happened in people who take this drug or drugs like it. This has been deadly in some cases. Talk with the doctor.
- In a study of patients 50 years of age or older who also had at least 1 heart disease risk factor, a drug like this one was compared to another drug for rheumatoid arthritis. The drug like this one had a higher risk of heart attack, stroke, and death than the other drug. Talk with the doctor.
- Blood clots have happened with drugs like this one, including with this drug. Sometimes, the blood clots were severe or deadly. Patients 50 years of age or older who also had at least 1 heart disease risk factor had a higher risk with drugs like this one than with certain other drugs. Talk with the doctor.
- 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.

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What is this drug used for?

- It is used to treat some types of arthritis.
- It is used to treat eczema.
- It is used to treat ulcerative colitis.
- It is used to treat ankylosing spondylitis.
- It is used to treat Crohn's disease.
- It is used to treat a certain artery problem called giant cell arteritis (GCA).
- 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 low red or white blood cell counts.
- If you have liver disease or if you have had hepatitis B or hepatitis C infections.
- If you have kidney disease.
- If you have an infection.
- 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 take any other drugs (prescription or OTC, natural products, vitamins). There are many drugs that interact with this drug, like certain drugs that are used for HIV, infections, or seizures.
- If you are breast-feeding. Do not breast-feed while you take this drug and for 6 days after your last dose.

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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.
- Different forms of this drug cannot be switched with each other. Do not switch between forms without checking with the doctor.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- If you have had hepatitis B before or carry the virus, talk with your doctor.
 Drugs like this one can cause the virus to become active. This can lead to very bad and sometimes deadly liver problems.
- Hepatitis testing needs to be done before taking this drug.
- Some viral infections like herpes zoster (shingles) 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.
- 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.
- Do not get a weakened bacteria like BCG for bladder cancer while you use this drug. Talk with your doctor.

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- High cholesterol has happened with this drug. If you have questions, talk with the doctor.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- Avoid grapefruit and grapefruit juice.
- The chance of skin cancer may be raised. Avoid lots of sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.
- Have your skin checked. Tell your doctor if you have any skin changes like a new wart, skin sore or reddish bump that bleeds or does not heal, or a change in the color or size of a mole.
- Holes in the GI (gastrointestinal) tract may rarely happen.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- If you may become pregnant, you must use birth control while taking this drug and for 4 weeks after your last dose. If you get pregnant, call your doctor right away.

Extended-release tablets:

 Some people have seen the tablet or parts of the tablet in the stool or ostomy output. If this happens, call the doctor.

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,

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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 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.
- 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 shingles like pain, itching, or tingling; fever; muscle aches; or rash (with or without blisters).
- Warm, red, or painful skin or sores on the body.
- A skin lump or growth.
- Dizziness or passing out.
- Feeling very tired or weak.
- Stomach pain that is new or worse.
- Change in bowel habits.
- Sudden change in eyesight.
- Cough.
- Fever or chills.
- Severe upset stomach or throwing up.
- Swelling in the arms or legs.
- Call your doctor right away if you have a swollen gland, night sweats, shortness of breath, or weight loss without trying.
- Call your doctor or get medical help right away if you have signs of heart attack or stroke. This includes chest pain or pressure, shortness of breath, dizziness or passing out, severe headache, weakness on 1 side of the body, trouble speaking or thinking, change in eyesight or balance, or drooping on 1 side of the face.

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 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, change of color, or pain in a leg or arm; or trouble speaking or swallowing.

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:

- Signs of a common cold.
- Upset stomach.
- Headache.
- Pimples (acne).
- Cold sores.
- Raised bumps where the hair comes out of the skin.

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.

All products:

Take with or without food.

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Extended-release tablets:

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

Oral solution:

- Measure liquid doses carefully. Use the measuring device that comes with this drug.
- An adapter will need to be put in the bottle. Use a new adapter with each new bottle. Do not take the adapter out of the bottle after it has been put in.
- Place the tip of the syringe into the mouth on the inside of the cheek. Gently push the plunger until all the drug is gone. Do not squirt into the back of the throat. This could cause gagging or choking.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next 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 in the original container at room temperature or in a refrigerator.
- Store 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.

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Oral solution:

- Keep lid tightly closed.
- 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.
- 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

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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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