

Ruxolitinib XR (Jakafi)

About This Medicine

RUXOLITINIB XR (RUX oh LI ti nib XR) treats blood and bone marrow cancers. 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 may also be used to treat a condition that can occur after a stem cell or bone marrow transplant (graft versus host disease). It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak (fatigue), and raise your risk of bleeding.
- Diarrhea (loose bowel movements)
- Headache
- Feeling dizzy
- Bruising
- Infection
- Swelling of the hands, feet, or any other part of the body

Note: 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

- Severe bone marrow suppression
- Risk of severe and life-threatening infections, including tuberculosis, hepatitis B, and shingles, in people with risk factors for these infections.
- A rare virus can cause an infection that affects your central nervous system and can be life-threatening. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, have trouble understanding or speaking, trouble thinking and/or memory loss, trouble walking, eyesight changes, numbness or lack of strength to your arms, legs, face, or body, or seizures. **If you start to have any of these symptoms let your care team know right away.**
- This medicine may raise your risk of getting another cancer, such as skin cancer.

- Increase in your cholesterol and triglyceride levels
- Typical signs and symptoms of your cancer may return when you stop treatment with ruxolitinib XR.
- 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.

Important Information

- Talk to your care team before stopping this medicine, it should be stopped gradually in most cases. You could experience serious side effects if stopped suddenly.

How to Take Your Medicine

- Swallow the medicine whole with or without food. Do not split, crush or chew tablets.
- **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.
- This medicine may be present in the urine, stool and 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 care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Protect from light. 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.



- If you are dizzy, get up slowly after sitting or lying.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help 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.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- Drink enough fluids to keep your urine pale yellow.
- If you 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). 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 your diarrhea.
- If you get any symptoms of shingles, call your care team right away. Do not put anything on it unless your care team says you may.

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 ruxolitinib XR. 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
- 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.**
- Extreme tiredness, agitation, or confusion
- Trouble understanding or speaking



- Trouble thinking and/or memory loss
- Blurry vision or changes in your eyesight
- Numbness or lack of strength to your arms, legs, face, or body
- Trouble walking
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- A headache that does not go away
- Easy bleeding or bruising
- 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.**
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- 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
- New skin lesions
- New wart
- Skin sore or reddish bump that bleeds or does not heal
- Change in size or color of a mole
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, trouble urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of shingles such as burning or shooting pain and tingling or itching, often on one side of the body or face. The pain can be mild to very bad.

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 or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 2 weeks after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.



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