Jakafi®
ruxolitinib (tablets)
5mg • 10mg • 15mg • 20mg • 25mg

EXPERIENCING UNCONTROLLED BLOOD COUNTS? JAKAFI MAY HELP.

If you are an adult with polycythemia vera and have blood counts that continue to fluctuate despite taking hydroxyurea, ask your doctor about the possibility of maintaining control and find out if Jakafi is right for you.

Jakafi® (ruxolitinib) is prescription medication used to treat adults with polycythemia vera who have already taken a medicine called hydroxyurea and it did not work well enough or they could not tolerate it.

Jakafi may help control hematocrit (percentage of red blood cell volume) and reduce spleen size.

Incyte

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QUESTIONS TO ASK AT YOUR NEXT DOCTOR'S APPOINTMENT

1 Why Jakafi for PV?

Low-dose aspirin therapy combined with phlebotomy is often the first treatment prescribed for patients with PV. Patients who have difficulty with phlebotomy, have an enlarged spleen, or experience severe PV-related symptoms may be prescribed HU, a chemotherapy drug.

Jakafi is not a chemotherapy drug. It's a targeted treatment that works to help keep the production of blood cells under control. In one clinical study, it was shown that approximately 1 in 4 patients with PV were intolerant to or did not benefit from HU treatment.

Discover what may be possible with Jakafi for the treatment of PV in patients who did not benefit from HU.

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Important Safety Information

Jakafi can cause serious side effects, including:

Low blood counts: Jakafi® (ruxolitinib) may cause low platelet, red blood cell, and white blood cell counts. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will do a blood test to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you develop or have worsening symptoms such as unusual bleeding, bruising, tiredness, shortness of breath, or a fever.

Please see Important Safety Information on pages 2-7 and click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

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2 What are some possible benefits of Jakafi treatment?

Jakafi may help control hematocrit and reduce spleen size in adults with PV who did not benefit from treatment with HU or could not tolerate it.*

Jakafi was compared against other standard therapies in a clinical trial of adults with PV who had already taken HU and it did not work well enough or they could not tolerate it. Treatment was said to be effective if Jakafi kept a patient's hematocrit level under control, while at the same time reducing spleen size by at least 35%.

At approximately 8 months, 23% of people treated with Jakafi (25/110) kept their hematocrit under control and had a reduction in spleen size of at least 35% compared to less than 1% of people (1/112) who received other treatments, including HU. At approximately 5 years, the 25 people who had a response at 8 months had a 74% chance of maintaining it.

*Every person is unique and results may vary. Talk to your doctor to see if your experience with PV makes you right to start taking Jakafi.

Important Safety Information (cont'd)

Infection: You may be at risk for developing a serious infection during treatment with Jakafi. Tell your healthcare provider if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters.

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3 What are the possible side effects when taking Jakafi?

The most common side effects of Jakafi for certain types of PV include: low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea.

These are not all the possible side effects of Jakafi. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Important Safety Information (cont'd)

Cancer: Some people have had certain types of non-melanoma skin cancers during treatment with Jakafi. Your healthcare provider will regularly check your skin during your treatment with Jakafi. Tell your healthcare provider if you develop any new or changing skin lesions during treatment with Jakafi.

Increases in cholesterol: You may have changes in your blood cholesterol levels during treatment with Jakafi. Your healthcare provider will do blood tests to check your cholesterol levels about every 8 to 12 weeks after you start taking Jakafi, and as needed.

Please see Important Safety Information on pages 2-7 and click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

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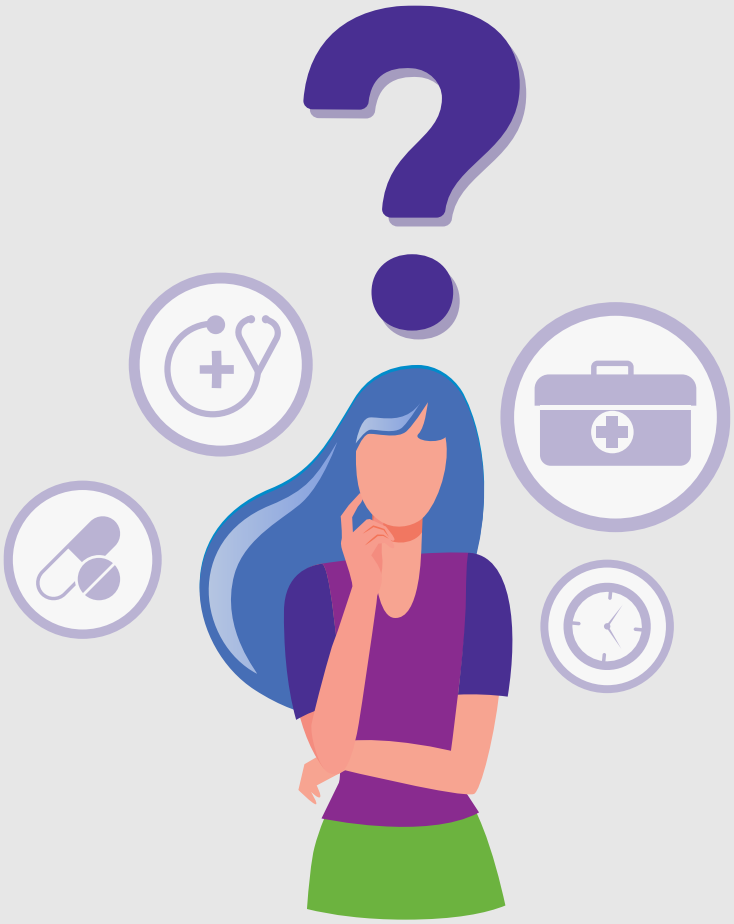
4 Is Jakafi right for me?



Be sure to speak with your doctor if you are taking HU but still experience:

- A continued need for phlebotomy to keep your hematocrit under control
- Blood cell counts frequently above normal
- An enlarged spleen that has not reduced in size
- Side effects such as leg ulcers or mouth ulcers

If you experience any of the symptoms above, you may want to talk to your doctor about Jakafi. If you and your doctor find that you do not benefit from HU, **ask if Jakafi may be right for you.**

Important Safety Information (cont'd)

Increased risk of major cardiovascular events such as heart attack, stroke or death in people who have cardiovascular risk factors and who are current or past smokers while using another JAK inhibitor to treat rheumatoid arthritis: Get emergency help right away if you have any symptoms of a heart attack or stroke while taking Jakafi, including: discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back, severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw, pain or discomfort in your arms, back, neck, jaw, or stomach, shortness of breath with or without chest discomfort, breaking out in a cold sweat, nausea or vomiting, feeling lightheaded, weakness in one part or on one side of your body, slurred speech

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Increased risk of blood clots: Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) have happened in people taking another JAK inhibitor for rheumatoid arthritis and may be life-threatening. Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with Jakafi, including: swelling, pain, or tenderness in one or both legs, sudden, unexplained chest or upper back pain, shortness of breath or difficulty breathing

Possible increased risk of new (secondary) cancers: People who take another JAK inhibitor for rheumatoid arthritis have an increased risk of new (secondary) cancers, including lymphoma and other cancers. People who smoke or who smoked in the past have an added risk of new cancers.

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Important Safety Information (cont'd)

The most common side effects of Jakafi include: for certain types of myelofibrosis (MF) and polycythemia vera (PV) – low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea; for acute GVHD – low platelet counts, low red or white blood cell counts, infections, and swelling; and for chronic GVHD – low red blood cell or platelet counts and infections including viral infections.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider for more information. Call your doctor for medical advice about side effects.

Before taking Jakafi, tell your healthcare provider about: all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had low white or red blood cell counts, have or had tuberculosis (TB) or have been in close contact with someone who has TB, had shingles (herpes zoster), have or had hepatitis B, have or had liver or kidney problems, are on dialysis, have high cholesterol or triglycerides, had cancer, are a current or past smoker, had a blood clot, heart attack, other heart problems or stroke, or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change your dose or stop taking Jakafi without first talking to your healthcare provider.

Women should not take Jakafi while pregnant or planning to become pregnant. Do not breastfeed during treatment with Jakafi and for 2 weeks after the final dose.

Please see the Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call **1-800-FDA-1088**.

You may also report side effects to Incyte Medical Information at 1-855-463-3463.

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