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

Understanding Polycythemia Vera

A guide for patients and caregivers

Please see the Important Safety Information beginning on page 16.
Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

What is PV?

PV is a rare, chronic blood cancer in which a person's body makes too many red blood cells, white blood cells, and platelets. PV is part of a group of diseases called **myeloproliferative neoplasms** or MPNs.

Too many red blood cells can cause the blood to thicken. Thicker blood doesn't flow normally through arteries and veins.

PV is a progressive disease. That means it may get worse over time. In some people, PV leads to other blood diseases, such as myelofibrosis (a disease in which scar tissue develops in the bone marrow) or leukemia. This potential for disease transformation is one reason why it is important to consistently monitor your condition and engage in regular conversations with your Healthcare Professional about any and all changes in your health.

Talk to your Healthcare Professional about any changes in your health—even if you don't think they're related to your PV.

Who gets PV?

Although PV can occur in persons of any age, it is more common later in life. The average age at which a person is diagnosed with PV is 60 years. PV affects slightly more men than women.

About **100,000 people** in the United States live with PV.

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

What causes PV?

No one knows exactly what causes PV. Evidence suggests that proteins known as Janus kinases, or JAKs, are involved. JAK proteins send signals that affect the production of blood in the bone marrow. When JAKs send too many signals, they cause the bone marrow to make too many blood cells. This is called ***overactive signaling***. Overactive JAK signaling is a key contributor to the development of PV.

In addition to making too many blood cells, overactive JAK signaling may result in the overproduction of certain proteins called ***cytokines*** (SIGH-toe-kines) in people with PV. Cytokines can cause inflammation. When your body has too many of these proteins, you may experience various symptoms related to PV.

Scientists think that overactive JAK signaling may be related to changes in the genes that make JAK proteins. These changes are called ***mutations***. Almost everyone with PV has a mutation of the Janus kinase 2 (*JAK2*) gene. Even if you don't have the *JAK2* mutation, you can still have PV.

Approximately **95% of people with PV** have a mutation that causes overactive JAK signaling.

Your Healthcare Professional may do a blood test to see if you have a ***mutation***, or change, in a gene that may cause PV.

Please see the Important Safety Information on pages 16–17. Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

What are common symptoms in PV?

Some people with PV do not have symptoms, while in others, PV symptoms can be severe.

Some symptoms of PV may be caused by having too many red blood cells, also known as ***hyperviscosity***. Hyperviscosity symptoms may include:

- Problems concentrating
- Headache
- Dizziness, vertigo, lightheadedness
- Reddening of the face or a burning feeling on the skin
- Blurred vision or blind spots
- Ringing in the ears
- Angina (chest pain)
- Shortness of breath
- Bleeding from the gums or heavy bleeding from small cuts

The overproduction of ***cytokines*** may also cause symptoms in people with PV. Cytokines can cause inflammation. When your body has too many cytokines, you may experience:

- Itching
- Night sweats
- Fatigue
- Bone pain
- Fever
- Unintentional weight loss

It's important to share *any and all* changes in your symptoms with your Healthcare Professional. New or changing symptoms may be a sign of disease progression.

It is important to talk to your Healthcare Professional about any and all symptoms you may have, even if you are not sure they are related to your PV. Talking to your Healthcare Professional about your symptoms helps you both:

- Understand how PV is affecting you
- Follow how your PV is changing over time
- Determine if your current PV management plan is working well enough for you

What happens in the body as a result of PV?

PV affects each person differently. Some patients with PV have an enlarged spleen. Your spleen helps your body fight infection and filters unwanted material, such as old or damaged blood cells. The increased number of blood cells caused by PV makes your spleen work harder than normal. This may cause the spleen to get bigger.

Because the spleen is located in your abdominal area, an **enlarged spleen** can cause a variety of symptoms that may include:

- Abdominal discomfort
- Pain under the left ribs
- An early feeling of fullness (early satiety)

In some people with PV, an enlarged spleen may also be a sign of disease progression, which means that your PV is changing or getting worse. That's why it's important to have your spleen size checked on a regular basis, throughout your PV journey.

Please see the Important Safety Information on pages 16–17. Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

What should I know about blood counts and PV?

In PV, a person's body produces an abnormal number of blood cells. This may include red blood cells, white blood cells, and platelets. Hematocrit is a measure of the volume of red cells in the blood and is stated as a percentage.

Keeping HCT at the right levels—usually below 45%—is an important goal in managing PV. Your Healthcare Professional may have a different HCT target for you based on your individual case.

"I always make sure that I have at least a little bit of documentation about what's been going on since my last visit. Have things gotten worse? Do I have new concerns?"

Chuck | Actual patient taking Jakafi for PV since 2020

This is Chuck's experience with Jakafi. Individual results may vary.

What aspects of PV should patients be keeping track of?

Because PV may change over time, keeping ongoing, detailed information about the various aspects of your condition can help you take an active role in managing your own care.

Keeping track of blood counts, symptoms, and the frequency of certain medical procedures (such as phlebotomy*), can help you spot trends in your health that may warrant a conversation with your Healthcare Professional. Remember sharing *any and all* changes in your health may help you identify possible signs of disease progression.

*Phlebotomy is a medical procedure that reduces blood counts by removing some blood from the body.

Please see the Important Safety Information on pages 16–17. Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

What goals may be a part of my PV management plan?

PV can be managed. Your Healthcare Professional will work with you to develop a PV management plan that's right for you. It may include:

- Keeping your hematocrit (volume of red blood cells) in a target range, such as under 45%
- Lowering other elevated blood cell counts
- Reducing the size of your enlarged spleen
- Managing symptoms
- If you are taking hydroxyurea, determining if it is not working well enough for you or you cannot tolerate it

Some possible treatments for PV include:

Low-dose aspirin and phlebotomy

These are often the first treatments prescribed. ***Phlebotomy*** is a procedure that removes blood from your body.

Hydroxyurea (HU), a chemotherapy drug

This drug is used to reduce the number of blood cells.

Jakafi® (ruxolitinib) is the *first FDA-approved treatment* for adults with PV who have already taken a medicine called HU and it did not work well enough or they could not tolerate it. Jakafi is ***not*** chemotherapy. It is a targeted treatment that works to help keep the production of blood cells under control.

Talk to your Healthcare Professional to see if Jakafi may be an option for you. Be sure to share all the medications, vitamins, and herbal supplements you are taking and all your medical conditions before taking Jakafi.

Discover Your Path to Possible

If you did not benefit from hydroxyurea (HU) or had to stop taking it because of side effects, it's important to take an active role in your own care. This includes talking to your Healthcare Professional if your current polycythemia vera (PV) treatment approach needs to change.

Donna | Actual patient taking Jakafi for PV since 2020

This is Donna's experience with Jakafi. Individual results may vary.

Move your journey in the direction that's right for you

When you're living with a rare disease like PV, the path you take to move your treatment journey forward depends on your individual condition as well as the decisions you make with your Healthcare Professional.

When discussing your treatment options with your Healthcare Professional, ask about Jakafi® (ruxolitinib).

Jakafi (JAK-ah-fye) is the *first medicine approved by the FDA* to treat adults with PV who have already taken a medicine called hydroxyurea and it did not work well enough or they could not tolerate it.

Jakafi can cause serious side effects including low blood counts and infection. Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Increases in blood cholesterol levels can also occur. In patients who took another JAK inhibitor to treat rheumatoid arthritis, there was an increased risk of potentially fatal cardiovascular events like heart attack or stroke in patients with risk factors for these events who smoke now or smoked in the past, as well as an increased risk of blood clots in legs or lungs and new (secondary) cancers like lymphoma, especially in patients who smoke now or smoked in the past. The most common side effects of Jakafi for certain types of myelofibrosis (MF) and polycythemia vera (PV) include: low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea. Call your Healthcare Professional for medical advice about side effects. **To learn more about these and other risks, please read the Important Safety Information beginning on page 16. Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.**

Is hydroxyurea failing to treat your PV effectively?

Although hydroxyurea (HU) is a commonly used chemotherapy medicine for PV, it may not be right for everyone. That's because not all people will benefit from HU or be able to tolerate it. In one clinical study, it was shown that approximately **1 in 4 patients** with PV was intolerant to or did not benefit from HU treatment.

Certain aspects of your condition may warrant a conversation with your Healthcare Professional about a possible change in your current PV treatment approach. For example, in a specific population of patients taking HU at the maximum dose and utilizing phlebotomy, **the following factors may be considered:**

- Continued need for phlebotomy
- Elevated hematocrit (HCT) levels
- Higher than normal white blood cell (WBC) counts
- Elevated platelet counts
- An enlarged spleen that has not reduced in size
- Unacceptable side effects from HU, such as mouth sores, leg ulcers, or gastrointestinal symptoms

If you are being treated with HU and phlebotomy and you and your Healthcare Professional determine that your blood counts are elevated or that you have an enlarged spleen, be sure to have a discussion about whether or not **Jakafi® (ruxolitinib) may be right for you**.

"I was initially started on hydroxyurea. My counts were hard to control."

Rob | Actual patient taking Jakafi for PV since 2017

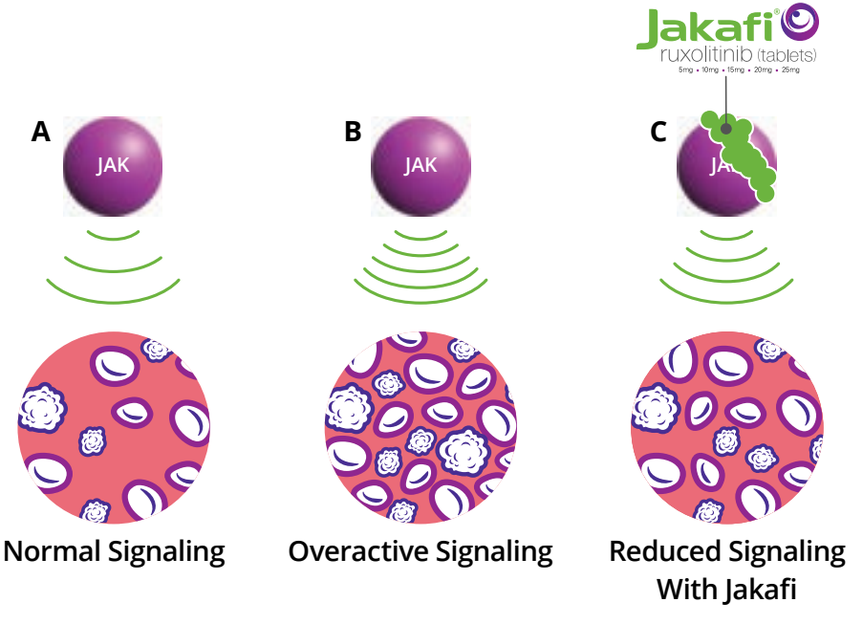
This is Rob's experience with Jakafi. Individual results may vary.

What is Jakafi?

Jakafi is the *first medicine approved by the FDA* 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. In these patients, Jakafi helps by keeping their hematocrit under control and reducing spleen size.

How does Jakafi work?

Jakafi is a targeted therapy that works by targeting JAKs, which control the production of blood cells. **(A)** JAK proteins send signals that affect the production of blood cells in the bone marrow. **(B)** When JAKs send too many signals, they cause the body to make the wrong number of blood cells. This chain of events is called overactive JAK signaling. **(C) Jakafi helps to reduce overactive JAK signaling to help keep the production of blood cells under control.** Jakafi may also help to reduce the size of an enlarged spleen.



Please see the Important Safety Information on pages 16–17. Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

What are some of the possible benefits of Jakafi for the treatment of PV?

Jakafi® (ruxolitinib) was compared against other standard therapies in a clinical trial of patients with PV who had already taken a medicine called hydroxyurea and it did not work well enough or they could not tolerate it. Treatment was considered effective if Jakafi kept a patient's hematocrit level (volume of red blood cells) under control, while also reducing spleen volume by at least 35%.

Hematocrit control

Reduced spleen size

The combination of these two measurements (hematocrit control and spleen size reduction) made up the ***primary endpoint***, or the main goal, of the study.

"My numbers are under control. They've been consistent for well over a year now."

Chuck | Actual patient taking Jakafi for PV since 2020

This is Chuck's experience with Jakafi. Individual results may vary.

Selected Safety Information

Jakafi can cause serious side effects including low blood counts and infection. Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Increases in blood cholesterol levels can also occur. In patients who took another JAK inhibitor to treat rheumatoid arthritis, there was an increased risk of potentially fatal cardiovascular events like heart attack or stroke in patients with risk factors for these events who smoke now or smoked in the past, as well as an increased risk of blood clots in legs or lungs and new

What were the results of the clinical trial?

After approximately 8 months of therapy:

23% (25 of 110) of patients in the group that received Jakafi compared with <1% (1 of 112) of patients in the group that received other treatments **kept their hematocrit under control and had a reduction in spleen volume of at least 35%**

60% (66 of 110) of patients in the Jakafi group **kept their hematocrit under control without phlebotomy** compared with 19% (21 of 112) of patients in the group that received other therapies

40% (44 of 110) of patients in the group receiving Jakafi **had at least a 35% reduction in their spleen volume** compared with <1% (1 of 112) of patients who received other therapies

Selected Safety Information (continued)

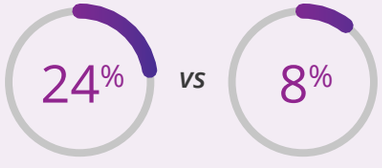
(secondary) cancers like lymphoma, especially in patients who smoke now or smoked in the past. The most common side effects of Jakafi for certain types of myelofibrosis (MF) and polycythemia vera (PV) include: low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea. Call your Healthcare Professional for medical advice about side effects. **To learn more about these and other risks, please read the Important Safety Information beginning on page 16. Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.**

How does Jakafi affect blood counts?

Because PV can affect not only red blood cells, but also white blood cells and platelets, researchers looked at all 3 blood counts (red blood cells, white blood cells, and platelets) and whether Jakafi helped control them. This was a secondary goal (or ***secondary endpoint***) of the clinical trial.

Results of the clinical trial demonstrated that **more patients receiving Jakafi® (ruxolitinib) achieved the combined goal of hematocrit control plus white blood cell count and platelet count within goal ranges** compared with other standard therapies.

After approximately 8 months of therapy:



24% (26 of 110) of patients in the group receiving Jakafi **achieved hematocrit control and had white blood cell and platelet counts within goal ranges** compared with 8% (9 of 112) of patients who received other therapies.

Every person is unique. How your PV progresses and how you will respond to Jakafi depends on your individual circumstances. Talk to your Healthcare Professional to learn more about how patients responded to Jakafi in the key clinical trial and ask about the potential long-term effects of Jakafi treatment.

Please see the Important Safety Information on pages 16-17. Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

What are some possible longer-term effects of Jakafi treatment?

Additional analyses of the key clinical trial for Jakafi were conducted at 20 months to look at the potential for PV patients to **maintain the primary response of hematocrit control plus spleen size reduction of at least 35%.**

Of the **25 patients who achieved the primary goal of hematocrit control plus spleen size reduction of at least 35%** at 8 months:

76% (19 of 25) ***maintained their response at approximately 20 months***

Of the **66 patients who achieved hematocrit control** at 8 months:

77% (51 of 66) ***maintained hematocrit control at approximately 20 months***

Of the **26 patients who achieved the secondary goal of hematocrit control and had white blood cell and platelet counts within goal range** at 8 months:

58% (15 of 26) ***maintained this response at approximately 20 months***

At approximately 5 years, the **25 people who achieved the primary goal at 8 months had a 74% chance of maintaining it**

Also at approximately 5 years, the **66 people who saw hematocrit control at 8 months had a 73% chance of maintaining it**

Important Safety Information

Jakafi® (ruxolitinib) 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.

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.

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.

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

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.

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 click here for 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**.

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

IncyteCARES for Jakafi: Helping You With Access and Support

Program for Eligible Patients Prescribed Jakafi® (ruxolitinib)

At IncyteCARES for Jakafi, our team can help with access and support for your treatment. We can help with access and support services, including:

Coverage Verification
We can check with a patient's insurance plan about their coverage for Jakafi and any out-of-pocket costs required.

Insurance Assistance
We can help patients understand how their insurance plan works. We can also offer information about prior authorization requirements and appealing insurance denials or restrictions.

Delivery Coordination
We can arrange to have the patient's prescription for Jakafi filled by an approved specialty pharmacy and delivered directly to either the patient's home or Healthcare Professional's office.

Savings Program
For patients with commercial prescription drug coverage—eligible patients pay as little as $0 per month, subject to certain limits.*

Ready to enroll in IncyteCARES for Jakafi?

Once you've been prescribed Jakafi, you can either:

- **Call** IncyteCARES for Jakafi to get started at **1-855-452-5234**

OR

- **Ask** your prescribing Healthcare Professional to enroll you

Note that not all patients who have been prescribed Jakafi are eligible to enroll in IncyteCARES for Jakafi or to receive all services we provide.

Learn more at IncyteCARES.com/Jakafi.

Patient Assistance Program (PAP)
Free product is offered to eligible patients who are uninsured or underinsured for Jakafi.*

Temporary Coverage
For insurance coverage delays, eligible patients can receive a free short-term supply of Jakafi.*

Patient Education and Support
Through our call center, IncyteCARES for Jakafi representatives can answer patient and caregiver questions about PV and Jakafi.

Connection to Other Support Services
For patients who need additional support beyond what we can provide directly, IncyteCARES for Jakafi can offer information about other independent organizations that may be able to help.

Have you been prescribed Jakafi?

Watch an informative video to see how our team can help! Visit WhatIsIncyteCARES.com or **scan the QR code** to the right.

Watch now!

*Terms and conditions apply. Terms of these programs may change at any time. No purchase contingencies or other obligations apply.

For more information about

visit **Jakafi-info.com**