Jakafi 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.

Please see Important Safety Information beginning on page 16 and the Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.
Living with polycythemia vera (PV)

DISCOVER YOUR PATH TO POSSIBLE

If you did not benefit from hydroxyurea (HU) or had to stop taking it because of side effects, you know the frustrations of living with a disease with so few treatment options.

Because PV is not always visible on the outside, friends and family may not understand how the disease is affecting you. Know that you are not alone.

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, be sure to ask about Jakafi. Jakafi (JAK-ah-fye) is the first and only medicine approved by the FDA to treat people with polycythemia vera (PV) who have already taken a medicine called hydroxyurea (HU) and it did not work well enough or they could not tolerate it.

This guide can help you learn more about PV. It also includes a detailed description of Jakafi, how it is thought to work, safety information, and what can be expected with treatment with Jakafi if you and your Healthcare Professional decide that Jakafi is right for you.

Jakafi can cause serious side effects including low blood counts and infection. Some people taking Jakafi have developed non-melanoma skin cancer. You may have changes in your blood cholesterol levels. These are not all the risks. Please read the Important Safety Information beginning on page 16 and the Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.
About polycythemia vera (PV)

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.

Talk to your Healthcare Professional about your disease and what you can expect over time.

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.

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.

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

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

Of the people with PV who are treated with HU, approximately 1 in 4 either do not respond well enough or cannot tolerate the treatment.
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 filter 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.

Some people with PV have no symptoms. In others, PV symptoms can be severe.

It is important to tell your Healthcare Professional about any symptoms you 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

What should I know about blood counts and PV?

Hematocrit is a measure of red cells in the blood and is stated as a percentage. One sign that your PV may not be controlled is a hematocrit level above 45%.

Your Healthcare Professional may have a different hematocrit target for you based on your individual case.

Keeping your blood counts—particularly your hematocrit—at the right levels is an important goal in managing PV.

How can PV affect me over time?

PV can be managed. Treatments are available that may help people keep their blood counts under control. However, PV is a chronic, progressive disease. That means it doesn’t go away and is likely to get worse over time.

In a very small number of 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 track and monitor your condition and engage in regular conversations with your Healthcare Professional.

Ask your Healthcare Professional about your hematocrit level and your treatment goals at your next visit.
What goals may be a part of my PV treatment plan?

Your Healthcare Professional will work with you to develop a PV treatment 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

What are some possible treatments for PV?

- **Low-dose aspirin and phlebotomy**
  Low-dose aspirin therapy is often the first treatment prescribed for patients with PV. It may be combined with phlebotomy.
  
  Phlebotomy is a procedure in which your blood cell counts are lowered by removing blood from your body.

- **Hydroxyurea (HU), a chemotherapy drug**
  Patients with PV who have difficulty with phlebotomy, have an enlarged spleen, or experience severe PV-related symptoms may be prescribed HU. HU is a chemotherapy drug that reduces the number of blood cells, including red blood cells (RBCs), white blood cells (WBCs), and platelets.

- **Jakafi® (ruxolitinib)**
  Jakafi is the *first and only FDA-approved* treatment for people with polycythemia vera (PV) who have already taken a medicine called hydroxyurea (HU) and it did not work well enough or they could not tolerate it.

  If you have PV and did not benefit from or could not tolerate HU, talk with your Healthcare Professional to see if Jakafi may be an option for you.

  **PV may be considered uncontrolled in some patients who have already taken HU. In one clinical study, it was shown that approximately 1 in 4 patients with PV do not benefit from HU treatment. When HU is not working to control PV or is not being tolerated, patients may experience any of the following:**

  - The need for phlebotomy in addition to HU to keep hematocrit levels below 45%
  - Other blood cell counts (WBCs and platelets) that are higher than they should be
  - Increasing disease-related signs or symptoms (eg, enlarged spleen)
  - Unacceptable side effects from HU

  If you have any questions, talk with your Healthcare Professional.
Approximately 95% of people with PV have a mutation called JAK2V617F that causes overactive JAK signaling.

What is Jakafi?

Jakafi is the first and only medicine approved by the FDA to treat patients with polycythemia vera (PV) who have already taken a medicine called hydroxyurea (HU) 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?

Overactive JAK signaling is a key contributor to the development of PV. Jakafi targets JAKs to reduce overactive JAK signaling.

Approximately 95% of people with PV have a mutation called JAK2V617F that causes overactive JAK signaling.
Possible benefits of Jakafi® (ruxolitinib)

What are some of the possible benefits of Jakafi for the treatment of polycythemia vera (PV)?

Jakafi was compared against other standard therapies in a clinical trial of patients with PV who had already taken a medicine called hydroxyurea (HU) 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%.

What were the results of the clinical trial?

After approximately 8 months of therapy:

23% of patients in the group that received Jakafi compared with <1% 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% of patients in the Jakafi group kept their hematocrit under control without phlebotomy compared with 19% of patients in the group that received other therapies

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

Jakafi can cause serious side effects including low blood counts and infection. Some people taking Jakafi have developed non-melanoma skin cancer. You may have changes in your blood cholesterol levels. These are not all the risks. Please read the Important Safety Information beginning on page 16 and the Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.
Possible side effects of Jakafi® (ruxolitinib)

What should I watch for when taking Jakafi® (ruxolitinib)?

Jakafi may cause serious side effects including low blood cell counts, which include platelets and red and white blood cells. Tell your Healthcare Professional right away if you develop or have worsening symptoms such as unusual bleeding, bruising, tiredness, shortness of breath, or a fever. You may also be at risk for developing a serious infection during treatment with Jakafi. Tell your Healthcare Professional if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters. Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your Healthcare Professional if you develop any new or changing skin lesions. You may have changes in your blood cholesterol levels. Your Healthcare Professional will do blood tests to check your cholesterol levels during your treatment with Jakafi.

The most common side effects of Jakafi include: low platelet count, low red blood cell counts, bruising, dizziness, and headache.
What important safety information do I need to know?

Jakafi can cause serious side effects, including:

Low blood counts: Jakafi® (ruxolitinib) may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests 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.

Skin cancers: Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your healthcare provider if you develop any new or changing skin lesions.

Increases in cholesterol: You may have changes in your blood cholesterol levels. Your healthcare provider will do blood tests to check your cholesterol levels during your treatment with Jakafi.

Continued on next page

The most common side effects of Jakafi include: low platelet count, low red blood cell counts, bruising, dizziness, headache.

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

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 tuberculosis (TB) or have been in close contact with someone who has TB, have or had hepatitis B, have or had liver or kidney problems, are on dialysis, had skin cancer, 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. Do not drink grapefruit juice while on Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

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.
FOR ELIGIBLE PATIENTS TAKING JAKAFI® (ruxolitinib)

IncyteCARES (Connecting to Access, Reimbursement, Education and Support) is an assistance program that can help support you when you’re starting Jakafi and throughout your treatment journey. As an eligible patient, you can work one-on-one with a registered nurse, OCN®, who can help you address a variety of specific needs:

Financial Assistance Options

- **Insurance assistance**
  - Help with understanding your insurance coverage for Jakafi and, if needed, providing information about appealing insurance denials and coverage restrictions

- **Copay/coinsurance assistance***
  - Pay as little as $25 per month if you have commercial or private insurance (eg, BCBS, Aetna)

- **Patient Assistance Program (PAP)**†
  - If you have no prescription coverage for Jakafi, you may be provided Jakafi free of charge

- **Temporary coverage**† for insurance delays
  - Help with getting Jakafi if you experience an insurance coverage delay

* Terms, conditions, and additional eligibility criteria apply. Valid prescription for Jakafi for an FDA-approved indication is required. Amount of savings for the purchase of Jakafi will not exceed $25,000 per year. Program benefits are subject to a monthly limit. Uninsured, cash-paying patients are not eligible. Patients insured through Medicare, Medicaid, and TRICARE are not eligible. See full criteria at IncyteCARES.com.

† Terms, conditions, and additional eligibility criteria apply. Valid prescription for Jakafi for an FDA-approved indication is required. Patients insured through Medicare, Medicaid, and TRICARE are not eligible. Free product is offered to eligible patients without any purchase contingency or other obligation.

**Education & Support**

- **Learn more about Jakafi**
  - Partner with a registered nurse, OCN®, who can answer many of your questions
  - Receive informative tips, tools, and resources about your condition and Jakafi

- **Delivery coordination for Jakafi**
  - An IncyteCARES nurse can coordinate delivery of Jakafi to your home or to your Healthcare Professional’s office

**Connection to Support Services**

- **IncyteCARES can identify and refer you to independent foundations**† that may be able to assist with:
  - Arranging transportation to and from medical appointments
  - Travel cost assistance
  - Copay/coinsurance
  - Emotional and educational support

† Some foundations or organizations may receive or have received donations from Incyte Corporation.

IncyteCARES is here to help
Get help on your journey with Jakafi. Enroll in IncyteCARES.

Connect with IncyteCARES today!
Visit: [www.IncyteCARES.com](http://www.IncyteCARES.com), or call 1-855-4-Jakafi (1-855-452-5234) Monday through Friday, 8 AM–8 PM, ET
Get more information about Jakafi.
Explore the possibilities at Jakafi-info.com.