

# Getting Started With Jakafi

A guide for patients and caregivers

Additional tools, information, and resources are available at Jakafi-info.com.



# DISCOVER YOUR

# Path to Possible

When it comes to moving your treatment journey forward, the path you take depends on your individual circumstances—as well as the decisions you make with your Healthcare Professional.

Discover what's possible with Jakafi<sup>®</sup> (ruxolitinib)—the *first FDA-approved prescription medicine* used to treat adults 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. Jakafi is also used to treat adults with certain types of myelofibrosis (MF).

#### What is PV?

PV is a rare, chronic blood cancer in which a person's bone marrow makes too many red blood cells. The body may also produce too many white blood cells and platelets, but the overproduction of red blood cells causes most of the problems associated with PV. For example, too many red blood cells can cause the blood to thicken. Thicker blood doesn't flow normally through arteries and veins.



Hematocrit (HCT) is a measure of how much space red blood cells take up in your blood and is stated as a percentage. Keeping hematocrit at the right levels—regularly below 45%—is an important goal in managing your PV. Your Healthcare Professional may have a different hematocrit target for you based on your individual case.

Please see the Important Safety Information on pages <u>8–9</u> and <u>Full Prescribing Information</u>, which includes a more complete discussion of the risks associated with Jakafi.



# "When I started hearing positive things about Jakafi...I said, maybe it's time to make that change."

**Chuck** | Actual patient taking Jakafi for PV since 2020 This is Chuck's experience with Jakafi. Individual results may vary.

#### What is MF?

MF is a rare, chronic blood cancer that affects the bone marrow that results in an abnormal production of blood cells, causing scar tissue to form. **Bone marrow** is the material inside the bone where blood cells are made.

As scar tissue builds up, the bone marrow can't make enough blood cells. The spleen, which is an organ near the stomach under the left ribs, partially takes over making blood cells. This may make the spleen get bigger, a condition called **splenomegaly** (splee-nuh-MEG-uh-lee).

In one clinical study, about 90% (681 of 768) of people living with primary MF had an enlarged spleen at diagnosis.



#### Be proactive about disease progression

PV and MF are considered to be progressive conditions, which means they may eventually change over time and get worse. It's important to track your condition over time and engage in regular conversations with your Healthcare Professional about *any and all* changes in your health. This includes changes in your symptoms, blood counts, and the frequency of certain medical procedures (eg, phlebotomies, blood transfusions, etc).



#### What is Jakafi?

Jakafi (JAK-ah-fye), also known as ruxolitinib, is a prescription medicine available as a pill. It is used 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 is the *first medicine approved by the FDA* for treatment of these patients.

Jakafi is also the *first FDA-approved medicine* used to treat adults with certain types of MF.

Jakafi is *not* chemotherapy. It is a targeted treatment that works to help keep the production of blood cells under control.

"I am fortunate to have found the right treatment for me."

Mayra | Actual patient taking Jakafi for high-risk MF since 2016 This is Mayra's experience with Jakafi. Individual results may vary.

#### How does Jakafi work?

PV and MF are rare, chronic blood cancers, and researchers are actively working to better understand them. **(A)** Evidence suggests that proteins known as Janus kinases, or JAKs, are involved. JAK proteins send signals that affect the production of blood cells. **(B)** When JAKs send too many signals, there is an abnormal production of blood cells. This is called **overactive signaling**. Overactive JAK signaling occurs in *both* PV and MF.



**(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.

#### How was Jakafi studied?

Jakafi was studied in separate clinical trials for both PV and MF. The results of these studies can be found in the next section of this brochure.

Because every patient is unique, it is important to remember that your results with Jakafi may vary. Always talk to your Healthcare Professional about your individual symptoms, how the disease affects you, your treatment plan, and any side effects that you experience.



#### **PV Possible Benefits**

In a clinical trial that studied patients with PV who could not tolerate HU or for whom HU did not work well enough, Jakafi<sup>®</sup> (ruxolitinib) kept *hematocrit* (volume of red blood cells) under control—reducing the need for phlebotomy—and reduced spleen size. This was the main goal of the study.





Reduced spleen size

In this same trial, **patients also achieved the combined goal of hematocrit control plus white blood cell count and platelet count** within goal ranges. Additional analyses of this trial showed that at approximately 5 years, many patients who had maintained their response of hematocrit control plus spleen reduction after 8 months had a good chance of maintaining those results.

This clinical study of Jakafi also included the collection of data on the symptoms of PV. This was not the main goal of the study.

**Every person is unique.** How you will respond to Jakafi depends on your individual circumstances. Talk to your Healthcare Professional about how patients responded to Jakafi in key clinical trials, including potential long-term effects of treatment with Jakafi.



"Jakafi is really doing what it's intended to do...decrease the production of red blood cells."

Donna | Actual patient taking Jakafi for PV since 2020 This is Donna's experience with Jakafi. Individual results may vary.

### MF Possible Benefits

In clinical trials that studied patients with intermediate or high-risk MF, Jakafi reduced spleen size and improved the core symptoms of MF.

The improvement in MF symptoms was based on the Total Symptom Score, or TSS, that combined the results for the following symptoms:



Jakafi has also been shown to help improve fatigue-related symptoms in patients with MF.

### Did the studies look at how long patients lived?

Long-term data, including overall survival, are also available for Jakafi. Patients were followed for up to 5 years. Talk to your Healthcare Professional to learn more about how patients responded to Jakafi in the key clinical trials and ask about the potential long-term effects of Jakafi treatment.

**Every MF journey is unique** and how you will respond to Jakafi depends on your individual circumstances. Individual results may vary.

For more information about clinical data for Jakafi, visit Jakafi-info.com.



#### **Important Safety Information**

#### Jakafi® (ruxolitinib) can cause serious side effects, including:

Low blood counts: lakafi® (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 lakafi 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 <u>Full Prescribing</u> <u>Information</u>, 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**.



# What should I tell my Healthcare Professional before taking Jakafi?

Before taking Jakafi<sup>®</sup> (ruxolitinib), tell your Healthcare Professional about all the medicines you take, including vitamins and herbal supplements. Taking Jakafi with certain other medicines may affect how Jakafi works. Especially tell your Healthcare Professional if you take medicines for fungal infections, bacterial infections, or HIV/AIDS.

Tell your Healthcare Professional about 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 (Jakafi should be taken after your 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.

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.

You should tell your doctor if you are pregnant or planning to become pregnant, or if breastfeeding.

#### How will I get Jakafi?

You will not be able to pick up Jakafi at a local pharmacy. Jakafi will come to you from a specialty pharmacy or a mail order pharmacy. It is important that you let your local pharmacist know that you are taking Jakafi, and it is also important to tell the specialty pharmacy about any other medicines, vitamins, and supplements you are taking. That way, your pharmacist can help you avoid any possible interactions between drugs.



#### Monitor your medications

It's important to keep track of the various medicines and supplements that you take and discuss them with your Healthcare Professional. Consider using a medication diary to help record and keep track of all prescription drugs, over-the-counter medications, and vitamins or natural/herbal supplements that you are taking. Be sure to bring this resource with you to your next appointment.



### "It's very important to track your counts."

**Rob** | Actual patient taking Jakafi for PV since 2017 *This is Rob's experience with Jakafi. Individual results may vary.* 



#### What dose should I take?



Take only the dose of Jakafi<sup>®</sup> (ruxolitinib) your Healthcare Professional prescribes, following your Healthcare Professional's instructions.

Bottles and tablets shown are not actual size.

Your Healthcare Professional will determine the appropriate dose of Jakafi for you by taking several factors into account, including:

- Whether you are taking Jakafi for MF or PV
- Results of your blood work
- Other medical conditions you may have
- Other medications you may be taking

#### Did you know...

*If you have PV,* it's important to discuss whether you may benefit from having the dose of Jakafi increased from the dose you started on to help control your PV. Talk to your Healthcare Professional about whether a higher dose might be right for you.

It is important to take the dose you were prescribed and as often as prescribed. If you miss a dose of Jakafi, take your next dose as scheduled. Do not take an additional dose.

If you take more than the prescribed dose, call your Healthcare Professional or go to the nearest hospital emergency department right away. Take the bottle of Jakafi with you.

#### How do I take Jakafi?

Take Jakafi exactly as your Healthcare Professional tells you. The starting dose of Jakafi is usually one tablet twice a day by mouth.

It is important to take both doses of Jakafi as prescribed because the medicine in Jakafi must stay in your body for a certain amount of time to work effectively.



In certain cases, your Healthcare Professional may start you at a lower dose or temporarily reduce your dose of Jakafi to once a day. Always follow your Healthcare Professional's directions.



It is important to take your medicine at about the same time each day. It may help you remember to take your Jakafi if you take it at the same time as you perform another daily activity, like brushing your teeth.



You can take Jakafi with or without food. Do not drink grapefruit juice while taking Jakafi. Grapefruit juice can affect the amount of Jakafi in your blood.

**Do not stop taking Jakafi without speaking with your Healthcare Professional.** However, if you start bleeding, stop taking Jakafi and call your Healthcare Professional immediately.



# How will my Healthcare Professional monitor me while I'm taking Jakafi?

Before you start treatment and periodically during treatment, your Healthcare Professional may perform a blood test called a complete blood count (CBC). The results of this test can help your Healthcare Professional:

- Determine the **appropriate starting dose** of Jakafi<sup>®</sup> (ruxolitinib) for you
- **Monitor your blood counts** during treatment to monitor the progression of your condition
- Adjust your dose of Jakafi, if necessary (most dosage adjustments will happen in the first couple of months but could happen any time during treatment)



# "Hy wasn't effective for me."

 Tami
 Actual patient taking Jakafi for high-risk MF since 2015

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

Your Healthcare Professional may monitor your blood cholesterol levels, as you may have changes in these levels during your treatment with Jakafi.

Please see the Important Safety Information on pages <u>8–9</u> and <u>Full Prescribing Information</u>, which includes a more complete discussion of the risks associated with Jakafi.

Your Healthcare Professional may also perform regular physical examinations, update your medical history, or ask if you are taking any new medicines. In some cases, your Healthcare Professional may perform a bone marrow biopsy. This test involves taking a sample of your bone marrow with a needle. The results of this biopsy can tell your Healthcare Professional if you have any scar-like, or fibrous, tissue in your bone marrow, which is a hallmark of myelofibrosis.

**It is important to talk to your Healthcare Professional** about how you are feeling and how your condition is affecting you, even if you're not sure that how you are feeling is caused by your condition.



# Talking to your Healthcare Professional helps you both:

- Understand how your condition is affecting you
- Follow how your condition is changing over time
- Discuss options for managing your condition



# What do I need to know about anemia (low red blood cell counts)?

Jakafi<sup>®</sup> (ruxolitinib) can cause anemia (low red blood cell counts). Anemia occurs when your red blood cell levels and hemoglobin (the part of the red blood cell that carries oxygen) levels become too low. When you start taking Jakafi, you should watch for the symptoms of anemia and discuss them with your Healthcare Professional.

#### Symptoms of anemia may include:

- Fatigue (extreme tiredness) or a lack of energy
- Shortness of breath

If you develop anemia, your Healthcare Professional will determine the best way to treat it.

#### How long will I need to take Jakafi?

If your Healthcare Professional decides that Jakafi is right for you, it is important that you continue to take it as prescribed. Jakafi is a long-term treatment.

Your Healthcare Professional may allow up to 6 months to see if Jakafi is working for you. If you do not see an improvement after 6 months of treatment, your Healthcare Professional may have you stop taking Jakafi.

### Is Jakafi right for you?

If you have PV and did not benefit from or cannot tolerate HU, talk with your Healthcare Professional about whether Jakafi may be right for you.

If you have intermediate or high-risk MF, *ask your Healthcare Professional if you are a possible candidate for treatment with Jakafi.* 



#### Follow dosing instructions

Always remember to take Jakafi—and any other medications exactly as prescribed by your Healthcare Professional. If you have any questions or concerns about your treatment plan, be sure to discuss them with your Healthcare Professional as soon as possible.

It is important to take Jakafi exactly as directed by your Healthcare Professional. Do not stop taking Jakafi without speaking with your Healthcare Professional. The only exception is that if you start bleeding, stop taking Jakafi and call your Healthcare Professional.



# IncyteCARES for Jakafi: Helping You With Access and Support

#### Program for Eligible Patients Prescribed Jakafi<sup>®</sup> (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.

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#### 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, MF, 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!

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





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