Jakafi[®] (ruxolitinib) is used to treat adults with certain types of myelofibrosis (MF).



Understanding Myelofibrosis

A guide for patients and caregivers



DISCOVER YOUR

Path to Possible

If you have been diagnosed with intermediate or high-risk myelofibrosis (MF), it's important to take an active role in your own care. That begins with learning about your disease and asking your Healthcare Professional if your current treatment approach needs to change.



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

When you're living with a rare disease like MF, 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 certain types of MF.

lakafi 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 MF and polycythemia vera include: low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea. Call vour 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 18 and Full **Prescribing Information.**



What is MF?

MF is a rare, chronic blood cancer that affects the bone marrow and the production of blood cells. People with MF typically have:

- Scarring in the bone marrow called *fibrosis* (fye-BRO-sis)
- Too few or too many blood cells
- Symptoms such as itching, night sweats, bone and muscle pain, abdominal discomfort, early feeling of fullness, and pain under the left ribs (also known as core symptoms)
- Enlarged spleen

Bone marrow is 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).

Your spleen helps your body fight infection and filter unwanted material, such as old or damaged blood cells. In some patients with MF, an enlarged spleen may also be a sign of disease progression, which means that your MF could be changing or getting worse.



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

Who gets MF?

Although MF can occur in people of any age, it is more common later in life. People are usually around 65 years old when they learn they have MF.

About **16,000 to 18,500** people in the United States live with MF.





"This is my life. I'm taking control. I'm going to find out what I need to know."

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

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

How is MF characterized?

People with MF fall along a spectrum with differing levels of bone marrow fibrosis, blood count abnormalities, and splenomegaly. Symptoms may range from having essentially no symptoms to having severe symptoms.



Watch Myelofibrosis, Spleen Size & You

Take a closer look at the various functions of the spleen and learn more about why spleen size is an important health focus for people with MF. **MyelofibrosisSpleenSizeAndYou.com**



What factors affect the course of MF?

The severity of MF (also called *risk level*) is determined by a number of factors (called *risk factors*) that include results of laboratory tests as well as clinical evaluation of your symptoms. These risk factors can affect the course—or progression—of your MF and may include:



, **Age** Being over 65



Symptoms The presence of certain symptoms

like fever, weight loss, and night sweats



Anemia

A low number of red blood cells based on lab testing



White blood cells Very elevated levels of white blood cells based on lab testing



Blood transfusions Need for blood transfusions

Blasts

lab testing

Platelets

Elevated levels of

or blasts, based on

Low platelet count

Genetic factors

Specific genetic

mutations

based on lab testing

immature blood cells,

The number of these factors that you have can help determine how your MF will be classified and treated. **If you have 1 or several of the above risk factors, you may already have intermediate or high-risk MF.**

Don't wait to discuss your MF risk level with your Healthcare Professional and ask if Jakafi[®] (ruxolitinib) may be right for you. In one clinical study, it was estimated that **nearly** 90% of patients with primary myelofibrosis were considered to be intermediate or high risk within 1 year of their MF diagnosis.

Is MF a progressive disease?

MF is a chronic, progressive disease. That means it doesn't go away, and it usually gets worse over time. In its early stages, MF may be silent. You may or may not experience symptoms even though the disease may be progressing. As the disease gets worse, however, the symptoms may also start to get worse.

This potential for disease progression is one reason why it is important to consistently monitor your MF and to regularly share *any and all* symptom changes with your Healthcare Professional. This information offers your Healthcare Professional valuable insights that may help guide your ongoing care.



For more information and to register for periodic updates, visit Jakafi-info.com today.



What causes MF?

MF is a complex condition, and researchers are still trying to discover its exact cause. Evidence suggests that proteins called Janus-associated kinases, or JAKs, are involved. JAKs send signals that affect the production of blood cells in the bone marrow.

When JAKs are working normally, they help the body make the right number of blood cells. When JAKs send too many signals, they cause the bone marrow to produce an abnormal number of blood cells. This is called *overactive signaling*. Overactive JAK signaling is a key contributor to the development of MF. When JAKs aren't working normally, they can also cause bone marrow scarring, an enlarged spleen, and other symptoms.

Patients with myelofibrosis also frequently have overproduction of certain proteins called *cytokines* (SIGH-toe-kines). Cytokines can cause inflammation. When your body has too many of these proteins, you may experience various symptoms related to MF.



Scientists think that overactive JAK signaling may sometimes be related to genetic changes. These changes are called *mutations*. About half of people with MF have a mutation of the Janus kinase 2 (JAK2) gene. However, even if you don't have the *JAK2* mutation, you still can have overactive signaling and MF.

Can MF develop from other myeloproliferative neoplasms (MPNs)?

MF belongs to a group of diseases called myeloproliferative neoplasms (MY-ah-lo-pro-LIF-er-uh-tiv NEE-o-plaz-uhms), or MPNs. If MF is a person's first MPN, then it is called *primary myelofibrosis*.

In other cases, another MPN, like polycythemia vera or essential thrombocythemia, can turn into MF. When this happens, it is called post-polycythemia vera MF or post-essential thrombocythemia MF. About 10% to 20% of patients with MF have these conditions.

What are common symptoms of MF?

Symptoms of MF can range from mild to severe. They may be caused by an enlarged spleen or by production of too many *cytokines*, proteins that cause inflammation.

Symptoms of an enlarged spleen include:



Symptoms caused by overproduction of cytokines in the body include:



Bone pain

These are not all the symptoms of MF.





*According to a web-based questionnaire sponsored by Incyte that included 207 patients in the US diagnosed with MF. This survey was intended to help evaluate patient disease burden in the MPN setting.



Is keeping track of MF symptoms important?

People living with MF may get used to their symptoms, making it difficult to notice when they are getting worse. That's why it's important to keep track of all aspects of your health on a regular basis so that you can more easily identify when something has changed. Communicating *any and all* symptom changes is important, as it can be helpful in identifying possible signs of disease progression.

In addition to monitoring symptoms, you may also want to keep track of key blood cell counts and medical procedures, such as blood transfusions. If you recognize any changes in your symptoms, blood count levels, or the frequency of blood transfusions, don't hesitate to discuss them with your Healthcare Professional.



One way to keep track of your MF is to use a tracking tool, symptom diary, or online tracker. However, no matter what tracking tool you use, don't hesitate to report any and all changes in your health to your Healthcare Professional—even if you're not sure that it's related to your MF.

Remember, regular tracking over time may help you discover important insights that can help you and your Healthcare Professional better understand the state of your MF—and ensure that your current treatment approach is the right one for you.

Talking to your Healthcare Professional about your symptoms helps you both:

- Understand how your MF is affecting you
- Follow how your MF is changing over time
- Discuss possible treatment options for managing your MF and its symptoms

How is MF treated?

Although MF is a chronic, progressive disease, it can be treated, and the symptoms can be managed.

Treatment goals for MF can include:



Reduction in the size of an enlarged spleen



Your Healthcare Professional will work with you to make a treatment plan that is right for you. One option may be Jakafi[®] (ruxolitinib). It is the *first prescription medicine approved by the FDA* to treat adults with certain types of MF.

If you have intermediate or high-risk MF, **ask your Healthcare Professional today if Jakafi may be right for you.**



"Myelofibrosis manifests itself differently in people. With me, it's an enlarged spleen, and...extreme itching."

Nick | Actual patient taking Jakafi for high-risk MF since 2011 This is Nick's experience with Jakafi. Individual results may vary.



What is Jakafi?

Before Jakafi, no drug therapies were approved to specifically treat certain types of MF. Instead, Healthcare Professionals used medicines approved for other diseases to try to help control the signs and symptoms of MF. In lower-risk MF patients who do not have symptoms, the "watch and wait" method may also be used.

Jakafi is the *first prescription medicine approved by the FDA* to treat adults with certain types of MF.

Jakafi is **not** chemotherapy. It is a targeted treatment that can work to help reduce the size of an enlarged spleen and improve the core symptoms of MF—including spleen-related symptoms in some patients.

How does Jakafi work?

(A) When proteins called JAKs are working normally, they help the body make the right number of blood cells. (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 has been shown to reduce spleen size and improve the core symptoms of certain types of MF—including spleen-related symptoms—in some patients. Jakafi has also been shown to help improve fatigue-related symptoms in patients with MF.



"My MF is now under my controlmine and Jakafi's."

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

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



Jakafi may cause low platelet, red blood cell, and white blood cell counts. Your healthcare provider will do a blood test to check your blood counts before you start Jakafi and regularly during your treatment.

Your Healthcare Professional may change your dose of Jakafi or stop your treatment based on the results of your blood tests. 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.



How was Jakafi studied?

In a clinical trial in adults with intermediate or high-risk MF, treatment with Jakafi was compared with treatment with placebo (sugar pill). Patients were then watched to see whether either treatment resulted in a reduction in the size of the spleen and also a decrease in core symptoms.

Treatment with Jakafi[®] (ruxolitinib) was considered effective if it reduced spleen size by a set goal of at least 35%. This was the main study goal, or *primary endpoint*.

Jakafi has been shown to reduce spleen size and improve the core symptoms of MF in some patients.

How does Jakafi reduce spleen size in MF?



In a clinical trial, **Jakafi reduced the size** of the spleen by a set goal of at least 35% in 42% (65 of 155) of people with MF when measured after 6 months of treatment. In contrast, less than 1% (1 of 154) of people taking a placebo (sugar pill) reached that goal.



Also in this trial, 99% (150 of 155) of people on Jakafi had some response to therapy. **This means that they had a reduction in spleen size even if it was less than the 35% goal achieved by some patients.**

How does Jakafi affect symptoms in MF?

In this same trial, Jakafi was also said to work if people reached a goal of 50% or greater improvement in their **Total Symptom Score**, or TSS, after 6 months of treatment. This assessment was an additional goal (or *secondary endpoint*) of the study.

The TSS represents a group of symptoms that were measured over a 6-month period. **The symptoms included in the TSS were:**

Night sweats | Abdominal discomfort | Itching | Pain under the left ribs | Bone/muscle pain | Early feeling of fullness



In the trial, **46% (68 of 148) of the people taking Jakafi saw at least a 50% improvement** in their TSS compared with only **5% (8 of 152)** of patients taking placebo.



In fact, **80% (116 of 145) of the patients taking Jakafi had some level of symptom improvement**—even if it wasn't 50%—this means their symptoms got somewhat better. Most of the people taking placebo actually saw their symptoms worsen.

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 MF and polycythemia vera include: low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea. Call vour 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 <u>18</u> and <u>Full</u> **Prescribing Information.**



Jakafi was also shown to reduce spleen-related symptoms

In the same clinical trial, Jakafi[®] (ruxolitinib) was also shown to reduce spleen-related symptoms in patients with MF. **After 6 months of treatment**, the percentage of patients with 50% or greater improvement in spleen-related symptoms included in the TSS was:

Early feeling of fullness

Pain under the left ribs

48% (69 of 155) of patients in the group that received Jakafi had early satiety (early feeling of fullness after eating) reduced by at least half compared with 11% (16 of 154) of patients in the group that received other treatments. 53% (72 of 155) of patients in the group that received Jakafi had pain under the left ribs reduced by at least half compared with 15% (21 of 154) of patients in the group that received other treatments.

48% (69 of 155) of patients in the group that received Jakafi had abdominal discomfort reduced by at least half compared with 9% (14 of 154) of patients in the group that received other treatments.

Abdominal

discomfort

RE

How does Jakafi help fatigue in MF?

In a separate analysis of the same trial, researchers also looked at whether treatment with Jakafi helped improve **fatigue-related symptoms** in patients with MF.

Fatigue-related MF symptoms included:

Tiredness | Exhaustion | Mental tiredness | Lack of energy

About 35% of the patients taking Jakafi experienced improvement in their fatigue-related MF symptoms and in the associated impacts of fatigue on their daily activities, ie, work, self-care, and exercise.

By contrast, 14% of patients in the placebo (sugar pill) group had a similar response.

Did the studies look at how long patients lived?

In key clinical trials for Jakafi, patients were followed for up to 5 years. One of the things the researchers looked at was the probability that patients taking Jakafi or other MF treatments would be alive at 1, 2, 3, and 5 years of treatment.

While *overall survival* (OS)—or the probability that patients taking Jakafi would be alive after a certain period of time—was not the main goal (or *primary endpoint*) of the key clinical trials for Jakafi, these long-term data were captured as a *secondary endpoint*.

These results are available in the Jakafi Prescribing Information; however, only the data from up to 3 years of follow-up are shown. This information should be reviewed along with your Healthcare Professional.

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



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 lakafi 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 accompanying 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 <u>www.fda.gov/medwatch</u>, or call **1-800-FDA-1088**.

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



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
- 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.

OR

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 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!

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