

PATIENT INFORMATION

JAKAFI® (JAK-ah-fye)
(ruxolitinib)
tablets, for oral use

JAKAFI XR™ (JAK-ah-fye EKS-AHR)
(ruxolitinib)
extended-release tablets, for oral use

What is JAKAFI or JAKAFI XR?

JAKAFI or JAKAFI XR is a prescription medicine used to treat:

- adults with certain types of myelofibrosis (MF).
- adults with polycythemia vera (PV) who have already taken a medicine called hydroxyurea and it did not work well enough or they could not tolerate it.
- adults and children 12 years of age and older with acute graft-versus-host-disease (aGVHD) who have taken corticosteroids and they did not work well enough.
- adults and children 12 years of age and older with chronic graft-versus-host-disease (cGVHD) who have taken one or two types of treatments and they did not work well enough.

It is not known if JAKAFI or JAKAFI XR is safe and effective in children for treatment of MF or PV.

Before taking JAKAFI or JAKAFI XR, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had low white or red blood cell counts
- have an infection
- have or had tuberculosis (TB), or have been in close contact with someone who has TB
- have had shingles (herpes zoster)
- have or had hepatitis B
- have a high level of fat in your blood (high blood cholesterol or triglycerides)
- have had a blood clot, heart attack, other heart problems, or stroke
- are a current or past smoker
- have had cancer in the past
- have or have had kidney problems or are on dialysis. If you are on dialysis, JAKAFI or JAKAFI XR should be taken after your dialysis.
- have or have had liver problems
- are pregnant or plan to become pregnant. It is not known if JAKAFI or JAKAFI XR will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if JAKAFI or JAKAFI XR passes into your breast milk. Do not breastfeed during treatment with JAKAFI or JAKAFI XR and for 2 weeks after the final dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking JAKAFI or JAKAFI XR with certain other medicines may affect how JAKAFI or JAKAFI XR works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take JAKAFI or JAKAFI XR?

- Take JAKAFI or JAKAFI XR exactly as your healthcare provider tells you.
- Do not change your dose or stop taking JAKAFI or JAKAFI XR without first talking to your healthcare provider. If you stop treatment with JAKAFI or JAKAFI XR, symptoms of your condition may return. See “What are the possible side effects of JAKAFI or JAKAFI XR?”
- **If you are prescribed JAKAFI:**
 - take JAKAFI 2 times a day or exactly as your healthcare provider tells you, with or without food.
 - JAKAFI may also be given through certain nasogastric tubes.
 - Tell your healthcare provider if you cannot take JAKAFI by mouth. Your healthcare provider will decide if you can take JAKAFI through a nasogastric tube.
 - Ask your healthcare provider to give you specific instructions on how to properly take JAKAFI through a nasogastric tube.
- **If you are prescribed JAKAFI XR:**
 - take JAKAFI XR 1 time a day with or without food.
 - swallow JAKAFI XR whole. Do not split, chew, or crush.
- If you miss a dose of JAKAFI or JAKAFI XR, take your next dose at your regular time. Do not take 2 doses at the same time.

- If you take too much JAKAFI or JAKAFI XR call your healthcare provider or go to the nearest hospital emergency room right away.
- You will have regular blood tests during your treatment with JAKAFI or JAKAFI XR. Your healthcare provider may change your dose of JAKAFI or JAKAFI XR or stop your treatment based on the results of your blood tests.

What are the possible side effects of JAKAFI or JAKAFI XR?

JAKAFI or JAKAFI XR can cause serious side effects including:

- **Low blood cell counts.** JAKAFI or JAKAFI XR can cause low platelet counts (thrombocytopenia), low red blood cell counts (anemia), and low white blood cell counts (neutropenia). If you develop bleeding, stop JAKAFI or JAKAFI XR and call your healthcare provider. Your healthcare provider will do a blood test to check your blood cell counts before you start JAKAFI or JAKAFI XR and regularly during your treatment with JAKAFI or JAKAFI XR. Tell your healthcare provider right away if you develop or have worsening of any of these symptoms:
 - unusual bleeding
 - bruising
 - tiredness
 - shortness of breath
 - fever
- **Infection.** You may be at risk for developing a serious infection during treatment with JAKAFI or JAKAFI XR. Tell your healthcare provider right away if you develop any of the following symptoms of infection:
 - chills
 - aches
 - fever
 - nausea
 - vomiting
 - weakness
 - painful skin rash or blisters
- **Worsening of symptoms after interrupting or stopping treatment.** Signs and symptoms of myelofibrosis may worsen after you stop treatment with JAKAFI or JAKAFI XR. Do not interrupt or stop treatment with JAKAFI or JAKAFI XR without talking to your healthcare provider. If you need to stop treatment with JAKAFI or JAKAFI XR, your healthcare provider may give you instructions for slowly stopping treatment. Tell your healthcare provider right away if you get any of the following signs and symptoms after stopping treatment with JAKAFI or JAKAFI XR:
 - fever
 - trouble breathing
 - feeling dizzy or lightheaded
 - weakness
 - night sweats
 - pain in left upper stomach (abdomen) area or left shoulder
- **Cancer.** Some people have had certain types of non-melanoma skin cancers during treatment with JAKAFI or JAKAFI XR. Your healthcare provider will regularly check your skin during your treatment with JAKAFI or JAKAFI XR. Tell your healthcare provider if you develop any new or changing skin lesions during treatment with JAKAFI or JAKAFI XR.
- **Cholesterol increases.** JAKAFI or JAKAFI XR may increase your blood cholesterol levels. Your healthcare provider will do blood tests to check your cholesterol levels about every 8 to 12 weeks after you start taking JAKAFI or JAKAFI XR, 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 get any symptoms of a heart attack or stroke during treatment with JAKAFI or JAKAFI XR, 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 or JAKAFI XR, 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 or JAKAFI XR in adults with certain types of MF and PV include:

- low platelet counts
- low red blood cell counts
- bruising
- dizziness
- headache
- diarrhea

The most common side effects of JAKAFI or JAKAFI XR in people with aGVHD include:

- low red blood cell counts
- low platelet counts
- low white blood cell counts
- infections
- swelling

The most common side effects of JAKAFI or JAKAFI XR in people with cGVHD include:

- low red blood cell counts
- low platelet counts
- infections, including viral infections

These are not all of the possible side effects of JAKAFI or JAKAFI XR.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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

How should I store JAKAFI or JAKAFI XR?

- Store JAKAFI or JAKAFI XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Tightly close the JAKAFI or JAKAFI XR bottle after you take your dose.
- Keep JAKAFI or JAKAFI XR bottle tightly closed to protect from light.

Keep JAKAFI and JAKAFI XR and all medicines out of the reach of children.

General information about the safe and effective use of JAKAFI or JAKAFI XR.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use JAKAFI or JAKAFI XR for a condition for which it is not prescribed. Do not give JAKAFI or JAKAFI XR to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

What are the ingredients in JAKAFI?

Active ingredient: ruxolitinib phosphate

Inactive ingredients: colloidal silicon dioxide, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycolate.

What are the ingredients in JAKAFI XR?

Active ingredient: ruxolitinib phosphate

Inactive ingredients: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium stearyl fumarate.

Manufactured for: Incyte Corporation, 1801 Augustine Cut-off, Wilmington, DE 19803

JAKAFI is a registered trademark of Incyte.

JAKAFI XR is a trademark of Incyte.

Patent Information: www.incyte.com/patents

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For more information call 1-855-463-3463 or go to www.jakafi.com.