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

Jakafi XR™ (ruxolitinib) extended release tablets
11mg • 22mg • 33mg • 44mg • 55mg

PV

For adults with polycythemia vera after inadequate response to or intolerance of hydroxyurea

Individualized dosing for JAKAFI

INDICATIONS AND USAGE

JAKAFI/JAKAFI XR (ruxolitinib) is for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Thrombocytopenia, Anemia and Neutropenia

- JAKAFI/JAKAFI XR can cause dose-related effects of thrombocytopenia, anemia and neutropenia. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated.
- Manage thrombocytopenia by reducing the dose or temporarily interrupting JAKAFI/JAKAFI XR. Platelet transfusions may be necessary.
- Patients developing anemia may require blood transfusions and/or dose modifications of JAKAFI/JAKAFI XR.
- Severe neutropenia (ANC $<0.5 \times 10^9$/L) was generally reversible by withholding JAKAFI/JAKAFI XR until recovery.

Please see Important Safety Information on the back cover for related and other risk information. Refer to the accompanying Full Prescribing Information for complete dosing recommendations for JAKAFI/JAKAFI XR.

HCP.Jakafi.com/PV-Dosing

Jakafi® (ruxolitinib) tablets | Jakafi XR® (ruxolitinib) extended-release tablets

For patients with polycythemia vera after inadequate response to or intolerance of hydroxyurea

Options you want for the efficacy and safety you expect[1]

PV

START here

A CBC and platelet (PLT) count must be performed before initiating therapy, every 2 to 4 weeks until doses are stabilized, and then as clinically indicated.

10	The recommended starting dose of JAKAFI for PV is 10 mg twice daily
JAKAFI is also available in tablets of:	
5	5 mg
15	15 mg
20	20 mg
25	25 mg

CBC, complete blood count; PV, polycythemia vera. Tablets shown are not actual size.

Early dose adjustments as needed help to optimize efficacy and safety

In the phase 3 RESPONSE* trial, which compared JAKAFI with best available therapy (BAT) in patients with PV who had an inadequate response to or were intolerant of hydroxyurea, the composite primary endpoint was defined as hematocrit (Hct) control without phlebotomy eligibility and a ≥35% spleen volume reduction as measured by CT or MRI.[1,2]

- 23% of patients receiving JAKAFI achieved the composite primary endpoint† at week 32 vs <1% for BAT‡ ($P < 0.0001$)[1]

66% (73/110) of patients treated with JAKAFI had dose adjustments from the recommended starting dose by week 32[3]

- The effectiveness and safety of JAKAFI XR has been established based on adequate and well-controlled studies of JAKAFI

See **SPECIAL POPULATIONS** tab for dosing information in patients with renal or hepatic impairment and for information on drug interactions.

OPTIMIZE to balance safety and efficacy

INCREASE DOSE

Dose modifications based on insufficient response

Doses may be increased in 5-mg twice-daily increments to a maximum of 25 mg twice daily.

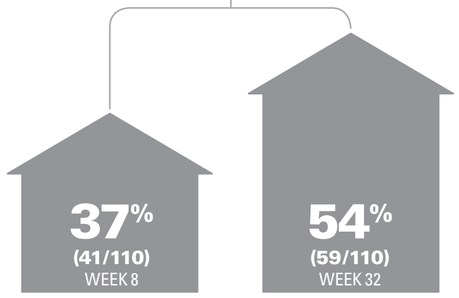
- Doses should not be increased during the first 4 weeks of therapy and not more frequently than every 2 weeks

Consider dose increases in patients who meet all of these criteria:

- ☑ Inadequate efficacy as demonstrated by one or more of the following:
  - Continued need for phlebotomy
  - White blood cell count greater than the upper limit of normal (ULN) range
  - PLT count greater than the ULN range
  - Palpable spleen that is reduced <25% from baseline
- ☑ PLT count ≥140 × 10^9/L
- ☑ Hemoglobin ≥12 g/dL
- ☑ ANC ≥1.5 × 10^9/L

From the RESPONSE trial

Percent of patients randomized to JAKAFI who *increased* from the starting dose[3]



MONITOR frequently — Monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated

DECREASE DOSE

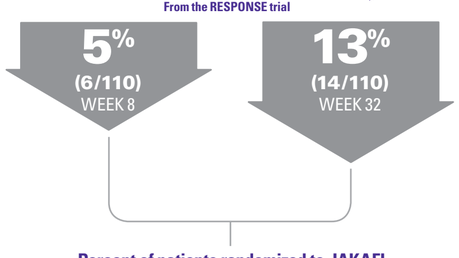
As shown in the chart below, dose reductions should be considered for:

- Hemoglobin <12 g/dL **or**
- PLT count <100 × 10^9/L

Dosing Recommendations	
If Hb 10 to <12 g/dL **and** PLT count 75 to <100 × 10^9/L	• Dose reductions should be considered, with the goal of avoiding dose interruptions for anemia and thrombocytopenia
If Hb 8 to <10 g/dL **or** PLT count 50 to <75 × 10^9/L	• Reduce dose by 5 mg twice daily • For patients on 5 mg twice daily, decrease the dose to 5 mg once daily
If Hb <8 g/dL **or** PLT count <50 × 10^9/L	• Interrupt JAKAFI dosing

Hb, hemoglobin; PLT, platelet.

From the RESPONSE trial



Percent of patients randomized to JAKAFI who *decreased* from the starting dose[3]

4% of patients randomized to JAKAFI discontinued treatment due to an adverse event[1,2]

INTERRUPT DOSE

Interrupt JAKAFI treatment for:

- Anemia (Hemoglobin <8 g/dL),
- Thrombocytopenia (PLT <50 × 10^9/L), **or**
- Neutropenia (ANC <1.0 × 10^9/L)

See **RESTARTING** tab for dose modifications.

Risk of Infection

Tuberculosis

- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting JAKAFI/JAKAFI XR until active serious infections have resolved. Observe patients receiving JAKAFI/JAKAFI XR for signs and symptoms of infection and manage promptly.
- Tuberculosis (TB) infection with JAKAFI/JAKAFI XR has been reported. Observe patients taking JAKAFI/JAKAFI XR for signs and symptoms of active TB and manage promptly. Prior to initiating, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting in patients with evidence of active or latent TB. Continuation during treatment of active TB should be based on the overall risk-benefit determination.

Please see Important Safety Information on the last page for related and other risk information. Please click here for Full Prescribing Information for complete dosing recommendations for JAKAFI/JAKAFI XR.

*The RESPONSE (Randomized study of Efficacy and Safety in POlycythemia vera with JAK iNhibitor ruxolitinib verSus bEst available care) trial was a randomized, open-label, active-controlled phase 3 trial comparing JAKAFI with BAT in 222 patients with polycythemia vera. Patients enrolled in the study had been diagnosed with polycythemia vera for at least 24 weeks, had an inadequate response to or were intolerant of hydroxyurea, required phlebotomy for Hct control, and exhibited splenomegaly. All patients were required to demonstrate Hct control between 40% and 45% prior to randomization. After week 32, patients were able to cross over to JAKAFI treatment.[1,2]

†The composite primary endpoint was defined as Hct control without phlebotomy eligibility and a ≥35% spleen volume reduction as measured by CT or MRI. To achieve the Hct control endpoint, patients could not become eligible for phlebotomy between weeks 8 and 32. Phlebotomy eligibility was defined as Hct >45% that is ≥3 percentage points higher than baseline or Hct >48% (lower value).[1,2]

‡BAT included hydroxyurea (60%), interferon/pegylated interferon (12%), anagrelide (7%), pipobroman (2%), lenalidomide/thalidomide (5%), and observation (15%).[1,2]

Restarting After Safety Interruption

After recovery of hematologic parameter(s) to acceptable levels, dosing may be restarted as shown in the table below

- Use the **most severe category** of patient's hemoglobin, PLT count, **or** ANC abnormality to determine the corresponding maximum restarting dose

Hb (g/dL)	PLT Count (× 10^9/L)	ANC (× 10^9/L)	Dosing Recommendations
<8	<50	<1.0	Continue hold
8 to <10	50 to <75	1.0 to <1.5	5 mg twice daily[a] or no more than 5 mg twice daily less than the dose that resulted in dose interruption
10 to <12	75 to <100	1.5 to <2.0	10 mg twice daily[a] or no more than 5 mg twice daily less than the dose that resulted in dose interruption
≥12	≥100	≥2.0	15 mg twice daily[a] or no more than 5 mg twice daily less than the dose that resulted in dose interruption

ANC, absolute neutrophil count; Hb, hemoglobin; PLT, platelet.

[a] Continue treatment for at least 2 weeks; if stable, dose may be increased by 5 mg twice daily.

Patients who required dose interruption while receiving a dose of 5 mg twice daily may restart at a dose of 5 mg twice daily or 5 mg once daily, but not higher, once:

- Hemoglobin is ≥10 g/dL,
- PLT count is ≥75 × 10^9/L, **and**
- ANC is ≥1.5 × 10^9/L

Dose management after restarting treatment

- Doses may be titrated, but the maximum total daily dose should not exceed 5 mg less than the dose that resulted in the dose interruption
- An exception to this is dose interruption following phlebotomy-associated anemia, in which case the maximum total daily dose allowed after restarting JAKAFI® (ruxolitinib) would not be limited

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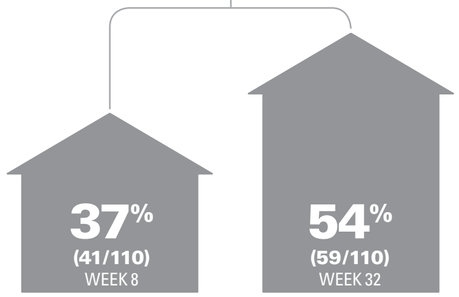
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From the RESPONSE trial

Percent of patients randomized to JAKAFI who *increased* from the starting dose[3]



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Monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated

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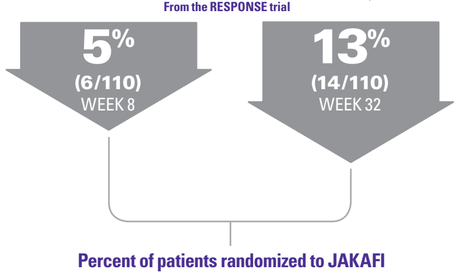
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Hb, hemoglobin; PLT, platelet.

From the RESPONSE trial



Percent of patients randomized to JAKAFI who *decreased* from the starting dose[3]

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Interrupt JAKAFI treatment for:

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Renal or hepatic impairment

Use a starting dose of 5 mg twice daily for patients with:

Hepatic Impairment: Mild, moderate, or severe (Child-Pugh class A, B, C)

Renal Impairment: Moderate (CrCl 30-59 mL/min) or severe (CrCl 15-29 mL/min)

- The recommended starting dose in patients with polycythemia vera who have end-stage renal disease and are on dialysis is 10 mg
- Additional dose modifications should be made with frequent monitoring of safety and efficacy
- Avoid use of JAKAFI® (ruxolitinib) in patients with end-stage renal disease (creatinine clearance, <15 mL/min) not requiring dialysis

Drug interactions

- Modify the dose of JAKAFI when coadministered with strong CYP3A4 inhibitors and fluconazole doses of ≤200 mg
- Avoid the use of fluconazole doses of >200 mg daily with JAKAFI
- Additional dose modifications should be made with frequent monitoring of safety and efficacy

For Patients Coadministered Strong CYP3A4 Inhibitors or Fluconazole Doses of ≤200 mg	Recommended Dose Modification
Starting dose for patients with PV:	5 mg twice daily
If on stable dose for patients with PV:	
≥10 mg twice daily	Decrease dose by 50% (round up to the closest available tablet strength)
5 mg twice daily	5 mg once daily
5 mg once daily	Avoid strong CYP3A4 inhibitor or fluconazole treatment, or interrupt treatment with JAKAFI for the duration of strong CYP3A4 inhibitor or fluconazole use

PV, polycythemia vera.

Please see Important Safety Information on the last page for related and other risk information. Please click here for Full Prescribing Information for complete dosing recommendations for JAKAFI/JAKAFI XR.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Progressive Multifocal Leukoencephalopathy

- Progressive multifocal leukoencephalopathy (PML) has occurred with JAKAFI/JAKAFI XR treatment. If PML is suspected, stop JAKAFI/JAKAFI XR and evaluate.

Herpes Zoster and Herpes Simplex

- Herpes zoster infection, reactivation and/or dissemination has been reported in patients receiving JAKAFI/JAKAFI XR. Advise patients about early signs and symptoms of herpes zoster and seek treatment. Monitor patients for the development of herpes simplex infections. If a patient develops evidence of dissemination of herpes simplex, consider interrupting treatment.

Hepatitis B

- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections.

Symptom Exacerbation Following Interruption or Discontinuation of Treatment

- When discontinuing JAK-Inhibitors, including JAKAFI/JAKAFI XR, myeloproliferative neoplasm-related signs and symptoms may flare. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, disseminated intravascular coagulation (DIC), or multi-organ failure. If any of these occur after discontinuation or while tapering JAKAFI/JAKAFI XR, evaluate and treat any intercurrent illness and consider restarting or increasing the dose. Instruct patients not to interrupt or discontinue JAKAFI/JAKAFI XR without consulting their physician. When discontinuing or interrupting JAKAFI/JAKAFI XR for reasons other than life-threatening toxicities, consider gradual tapering rather than abrupt discontinuation.

Non-Melanoma Skin Cancer (NMSC)

- NMSC including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations.

Lipid Elevations

- Treatment with JAKAFI/JAKAFI XR has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiation.

Major Adverse Cardiovascular Events (MACE)

- Another JAK-inhibitor has increased the risk of major adverse cardiovascular events (MACE), including cardiovascular death, myocardial infarction, and stroke (compared to those treated with TNF blockers), in patients with rheumatoid arthritis, a condition for which JAKAFI/JAKAFI XR is not indicated. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur.

Thrombosis

- Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis (DVT), pulmonary embolism (PE), and arterial thrombosis (compared to those treated with TNF blockers), in patients with rheumatoid arthritis, a condition for which JAKAFI/JAKAFI XR is not indicated. In patients with myelofibrosis (MF) and polycythemia vera (PV), the rates of thromboembolic events were similar in JAKAFI/JAKAFI XR and control treated patients. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately.

Secondary Malignancies

- Another JAK-inhibitor has increased the risk of lymphoma and other malignancies, excluding NMSC (compared to those treated with TNF blockers), in patients with rheumatoid arthritis, a condition for which JAKAFI/JAKAFI XR is not indicated. Patients who are current or past smokers are at additional increased risk.

Adverse Reactions

- In polycythemia vera, the most common hematologic adverse reactions (incidence >20%) were thrombocytopenia and anemia. The most common nonhematologic adverse reactions (incidence ≥15%) were bruising, dizziness, headache and diarrhea.

Drug Interactions

- Avoid concomitant use with fluconazole doses greater than 200 mg. Dose modifications may be required when administering fluconazole doses of 200 mg or less, or with strong CYP3A4 inhibitors, or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy.

Pregnancy

- Use during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking JAKAFI/JAKAFI XR should not breastfeed during treatment and for 2 weeks after the final dose.

Please see accompanying Full Prescribing Information for JAKAFI/JAKAFI XR.

References: 1. JAKAFI/JAKAFI XR Prescribing Information. Wilmington, DE: Incyte Corporation. **2.** Vannucchi AM, Kiladjian JJ, Griesshammer M, et al. Ruxolitinib versus standard therapy for the treatment of polycythemia vera. *N Engl J Med.* 2015;372(5):426-435. **3.** Data on file. Incyte Corporation. Wilmington, DE.

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