Product Specifications and Distribution

Jakafi XR™ (ruxolitinib) extended release tablets

11mg • 22mg • 33mg • 44mg • 55mg

Manufactured By

Incyte Corporation - **1-855-463-3463**

Marketed By

Incyte Corporation - **www.Incyte.com**

Product Name

JAKAFI XR

Generic Name

Ruxolitinib

Product Website

www.hcp.jakafi.com

Wholesale Acquisition Cost (WAC)[1]

<<$18,190 / bottle (all strengths)>>
WAC current as of <<May 2026>>



Tablets are not actual size. For illustration purposes only.

Product Barcodes

Use the barcodes shown here to facilitate the loading of JAKAFI XR into your EHR platform.

11 mg

CA-2767-01
133617

22 mg

CA-2768-01
133619

33 mg

CA-2769-01
133620

44 mg

CA-2770-01
133621

55 mg

CA-2771-01
133622

INDICATIONS AND USAGE

- JAKAFI®/JAKAFI XR™ (ruxolitinib) is for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF in adults.
- JAKAFI®/JAKAFI XR™ is for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea.
- JAKAFI®/JAKAFI XR™ is for treatment of steroid-refractory acute graft-versus-host disease (aGVHD) in adult and pediatric patients 12 years and older.
- JAKAFI®/JAKAFI XR™ is for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

EHR, electronic health record.

Please see additional Important Safety Information on pages 5 and 6, and Full Prescribing Information for JAKAFI/JAKAFI XR.

Dosing[2]

Detailed guidelines for dosing and dose modifications are provided in the Full Prescribing Information.

- The recommended starting dose for **MF** is based on platelet (PLT) count. Perform a complete blood count (CBC) before initiating JAKAFI XR therapy, every 2 to 4 weeks until doses are stabilized, and then as clinically indicated

PLT Count (x 10^9/L)	Recommended Starting Dose
50 to <100	11 mg orally once daily
100 to 200	33 mg orally once daily
>200	44 mg orally once daily

- The recommended starting dose for **PV** is 22 mg given orally once daily
- The recommended starting dose for **aGVHD** is 11 mg given orally once daily. Monitor CBC, including PLT count and ANC, and bilirubin prior to initiating therapy
  - Consider increasing the dose to 22 mg once daily after at least 3 days of treatment if the ANC and PLT counts are not decreased by ≥50% relative to the first day of dosing with JAKAFI XR
- The recommended starting dose for **cGVHD** is 22 mg given orally once daily. Monitor CBC, including PLT count and ANC, and bilirubin prior to initiating therapy

Diagnosis Codes[3]

	ICD-10-CM Codes
MF	D75.81
PV	D45
aGVHD	D89.810
cGVHD	D89.811
aGVHD on cGVHD	D89.812
GVHD, unspecified	D89.813

The healthcare provider is responsible for determining appropriate codes for billing. The information contained in this reference document is not intended to be definitive or exhaustive, or to serve as a replacement for the guidance of a qualified professional advisor.

Important Safety Considerations[2]

- Treatment with JAKAFI/JAKAFI XR can cause thrombocytopenia, anemia, and neutropenia, which are each dose-related effects. Perform a pre-treatment CBC and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated. In patients with cytopenias, consider dose reductions or temporarily withholding JAKAFI/JAKAFI XR or transfusions, as clinically indicated

ANC, absolute neutrophil count; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

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How Supplied/Storage and Handling[2]

JAKAFI XR™ (ruxolitinib) tablets are available as follows:

NDC Number	Dose Strength	Description and Photo	Unit of Sale	Approximate Unit of Weight	Approximate Unit Dimensions (L x W x H)
50881-011-08	11 mg	 Round light pink tablet with "I" on one side and "11" on the other	30-count bottle	[31 g]	1 7/8" × 1 7/8" × 3 1/4"
50881-022-08	22 mg	 Round light yellow tablet with "I" on one side and "22" on the other	30-count bottle	[31 g]	
50881-033-08	33 mg	 Round pink tablet with "I" on one side and "33" on the other	30-count bottle	[33 g]	
50881-044-08	44 mg	 Round grey tablet with "I" on one side and "44" on the other	30-count bottle	[33 g]	
50881-055-08	55 mg	 Round yellow tablet with "I" on one side and "55" on the other	30-count bottle	[33 g]	

Tablets shown are not actual size.

- Store at 20 °C to 25 °C (68 °F to 77 °F); excursions permitted between 15 °C and 30 °C (59 °F and 86 °F)
- Dispense in a tight container. Protect from light

Distribution

JAKAFI XR is available through a limited network of specialty distributors and specialty pharmacies.

CardinalHealth · ASD Healthcare AmerisourceBergen · McKESSON

accredo · OPTUM · Onco360 Oncology Pharmacy · Biologics · CVS Caremark Specialty Pharmacy · CenterWell Pharmacy · allianceRx Walgreens Pharmacy

- JAKAFI XR is available through the following Specialty GPOs: [VitalSource, ION Solutions, and Onmark and Unity]

Important Safety Considerations[2] (continued)

- 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. Use active surveillance and prophylactic antibiotics according to clinical guidelines

GPO, group purchasing organization; NDC, National Drug Code.

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Contact Information

Product Information
For additional information on JAKAFI XR, please contact:

Phone: 1-855-463-3463
Email: MedInfo@Incyte.com

Product Returns
Credit for returns is subject to Incyte's current Specialty Return Goods Policy. Please request a Return Goods Authorization by calling:

1-855-751-7958

US Medical Information Inquiries
For all medical information requests, please contact Incyte Medical Information:

Phone: 1-855-463-3463
Email: MedInfo@Incyte.com

Adverse Event Reporting
Contact Incyte or the FDA to report an adverse event.

Incyte
Phone: 1-855-463-3463
Email: MedInfo@Incyte.com

FDA
Phone: 1-800-FDA-1088
Web: www.fda.gov/medwatch

Patient Support Program

IncyteCARES

IncyteCARES for JAKAFI/JAKAFI XR Supports Eligible Patients During Treatment

The IncyteCARES mission is to help patients start and stay on therapy by assisting with access and as-needed support.

IncyteCARES can help patients understand their health insurance coverage, can provide reimbursement support, and can offer savings, financial assistance, and support options for eligible patients*

The IncyteCARES Team Is Available by Phone Every Weekday

Call 1-855-452-5234, Monday to Friday, 8 AM - 8 PM ET

Visit HCP.IncyteCARES.com/JAKAFI to learn more

*Terms and conditions apply. Program terms may change at any time.

FDA, Food and Drug Administration.

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Important Safety Information

Warnings and Precautions

Thrombocytopenia, Anemia and Neutropenia

- JAKAFI®/JAKAFI XR™ (ruxolitinib) 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.

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.

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.

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Important Safety Information (continued)
Warnings and Precautions (continued)

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 myelofibrosis, 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.
- 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.
- In acute graft-versus-host disease, the most common hematologic adverse reactions (incidence >50%) were anemia, thrombocytopenia and neutropenia. The most common nonhematologic adverse reactions (incidence >50%) were infections (pathogen not specified) and edema.
- In chronic graft-versus-host disease, the most common hematologic adverse reactions (incidence >35%) were anemia and thrombocytopenia. The most common nonhematologic adverse reactions (incidence ≥20%) were infections (pathogen not specified) and viral infections.

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 additional Important Safety Information on page 5 and Full Prescribing Information for JAKAFI/JAKAFI XR.

To learn more, visit hcp.jakafi.com.

References: 1. Data on file. Incyte Corporation. **2.** JAKAFI/JAKAFI XR Prescribing Information. Wilmington, DE: Incyte Corporation. **3.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Accessed April 22, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes

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