

For adults with intermediate- or high-risk MF¹

Intervene with Jakafi at diagnosis

NCCN
GUIDELINES[®]
RECOMMENDED

Ruxolitinib (Jakafi) is a Category 2A treatment option for both symptomatic lower-risk[†] and higher-risk MF – in patients with platelets $\geq 50 \times 10^9/L$.^{2‡}*

*Category 2A: Based upon lower-level evidence compared to Category 1; there is uniform NCCN consensus that the intervention is appropriate.²

[†] Lower-risk MF is defined as low or intermediate-1 risk based on DIPSS, DIPSS-Plus, and MYSEC-PM, low or intermediate risk based on MIPSS-70 (threshold of ≤ 3 prognostic variable points), and very low, low, or intermediate risk based on MIPSS-70+ (version 2.0; threshold of ≤ 3 prognostic variable points).²

[‡] In patients who are not transplant candidates.

Indications and Usage

Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults.

Important safety considerations

- Treatment with Jakafi can cause 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. In patients with cytopenias, consider dose reductions or temporarily withholding Jakafi or transfusions, as clinically indicated
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Evaluate patients prior to and while receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines

Please see related and other Important Safety Information on pages 12-13.

Please [click here](#) for Full Prescribing Information.

*Experience with Jakafi
since FDA approval^{3§}*



[§] Estimated total patients treated with commercially available Jakafi in the United States since 2011.³

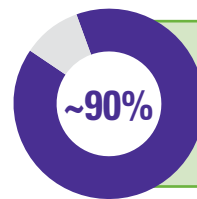
See [Full Prescribing Information](#) for FDA-approved indications.

When do you intervene in patients with intermediate- or high-risk MF?

Myelofibrosis (MF) is a serious disease that may require active management at diagnosis⁴

In MF, the presence of any one of the following risk factors* indicates that a patient is already intermediate risk^{5,6}:

- Hemoglobin level <10 g/dL
- Leukocyte count >25 × 10⁹/L
- Age >65 years
- Red cell transfusion dependency
- Circulating blast cells ≥1%
- Platelet count <100 × 10⁹/L
- Constitutional symptoms
- Unfavorable karyotype



In a study of patients with primary MF, approximately 90% (375/428) of evaluable patients were considered to be **intermediate or high risk within 1 year of diagnosis⁵**

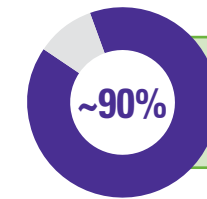
* As included in the Dynamic International Prognostic Scoring System Plus tool.

Risk for thrombocytopenia, anemia, and neutropenia

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. 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. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia (ANC <0.5 × 10⁹/L) was generally reversible by withholding Jakafi until recovery

New or increasing splenomegaly is considered to be a marker of disease progression⁷

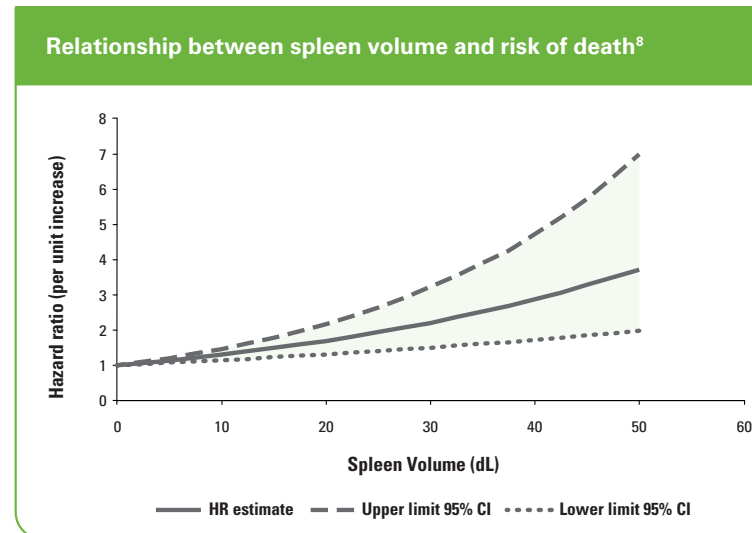
A palpable spleen of ≥5 cm below the left costal margin constitutes progressive disease,* according to the IWG-MRT and ELN response criteria⁷



In a study of 1054 patients with primary MF, approximately 90% of patients for whom data were available **had palpable splenomegaly at diagnosis⁶**

Data were available for 768 patients, 681 of whom had palpable splenomegaly.⁶

Larger baseline spleen volume was associated with incremental increases in the risk of death⁸



- In a post hoc, pooled analysis of overall survival in the COMFORT studies (N=528), there was a 14% increase in the risk of death for each additional 5 dL in spleen volume at baseline over 3 years (HR, 1.14; 95% CI, 1.07-1.21)^{8†}
- These increases were seen irrespective of treatment⁸

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Palpating the spleen at diagnosis in all patients with MPNs²

Imaging, including ultrasound, may be appropriate for patients with a body habitus which precludes palpation⁹

CI, confidence interval; CT, computed tomography; ELN, European LeukemiaNet; HR, hazard ratio; IWG-MRT, International Working Group-Myeloproliferative Neoplasms Research and Treatment; MF, myelofibrosis; MRI, magnetic resonance imaging; NCCN, National Comprehensive Cancer Network.

* Progressive disease assignment for splenomegaly requires confirmation by CT or MRI showing a ≥25% increase in spleen volume from baseline. Baseline values for both physical examination and imaging studies refer to pretreatment baseline and not to posttreatment measurements.⁷

† A post hoc pooled analysis of overall survival with ruxolitinib was performed using data from the two phase 3 studies: COMFORT-I, a randomized, double-blind, placebo-controlled study with 309 patients with intermediate-2-risk or high-risk MF, and COMFORT-II, a randomized, open-label study with 219 patients with intermediate-2-risk or high-risk MF. The primary endpoint in both studies was the proportion of patients achieving a ≥35% reduction in spleen volume (measured by CT or MRI) at week 24 in COMFORT-I and at week 48 in COMFORT-II.^{9,10,11}

Please see related and other Important Safety Information on pages 12-13. Please [click here](#) for Full Prescribing Information.



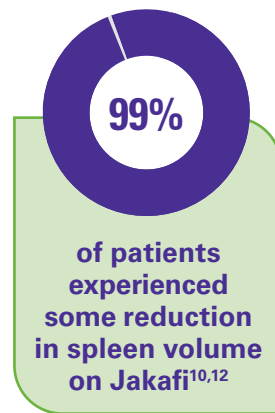
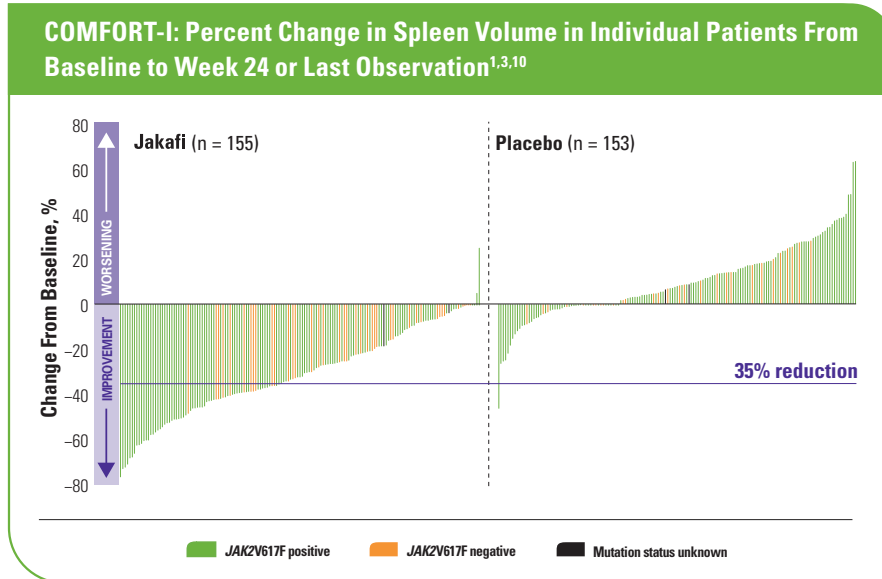
For adults with intermediate- or high-risk MF¹

Intervene with Jakafi[®] (ruxolitinib) at diagnosis

COMFORT-I Primary Endpoint*

42% of patients receiving Jakafi achieved a $\geq 35\%$ reduction in spleen volume at week 24 vs 0.7% of patients receiving placebo ($P < 0.0001$)^{1,10}

- 4.4 years median duration of spleen response among primary responders (n = 65)^{3†}



Most patients receiving placebo experienced an increase in spleen volume.^{1,12}

Each bar represents an individual patient's response. From *New England Journal of Medicine*, Verstovsek S, Mesa RA, Gotlib J, et al, A double-blind, placebo-controlled trial of ruxolitinib for myelofibrosis, 366(9), 799-807. Copyright © 2012 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

COMFORT-II Primary Endpoint[‡]

29% of patients receiving Jakafi achieved a $\geq 35\%$ reduction in spleen volume at week 48 vs 0% of patients receiving best available therapy[§] ($P < 0.0001$)^{1,11}

* COMFORT-I (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-I) was a randomized, double-blind, placebo-controlled phase 3 study with 309 patients with intermediate-2-risk or high-risk MF. The primary endpoint was the proportion of patients achieving a $\geq 35\%$ reduction in spleen volume from baseline to week 24 as measured by CT or MRI.^{1,10}

† Duration of spleen response was defined as the interval between the first spleen response measurement that was a $\geq 35\%$ reduction from baseline and the date of the first measurement that was no longer a $\geq 35\%$ reduction from baseline that was also a $>25\%$ increase from nadir.³

‡ COMFORT-II (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-II) was a randomized, open-label phase 3 study with 219 patients with intermediate-2-risk or high-risk MF. The primary endpoint was the proportion of patients achieving a $\geq 35\%$ reduction in spleen volume from baseline at week 48 as measured by CT or MRI.^{1,11}

§ Best available therapy in COMFORT-II included hydroxyurea (46.6%) and glucocorticoids (16.4%), as well as no medication, anagrelide, epoetin alfa, thalidomide, lenalidomide, mercaptopurine, thioguanine, danazol, peginterferon alfa-2a, interferon- α , melphalan, acetylsalicylic acid, cytarabine, and colchicine.³

Risk of infection

- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, 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 Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination

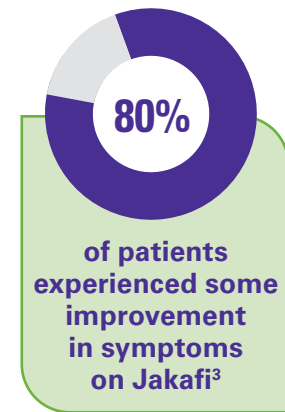
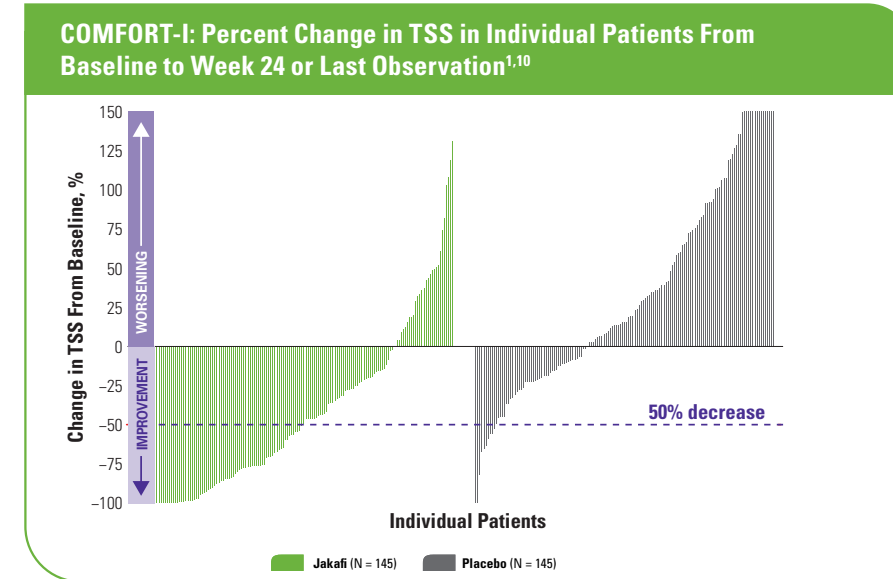
Significantly more patients

Achieved a $\geq 50\%$ improvement in Total Symptom Score compared with placebo

COMFORT-I Secondary Endpoint*

46% of patients receiving Jakafi achieved a $\geq 50\%$ improvement in Total Symptom Score (TSS) at week 24 vs 5% of patients receiving placebo ($P < 0.0001$)^{1,10}

- Median time to symptom response was <4 weeks for patients receiving Jakafi¹



Most patients receiving placebo had worsening of symptoms.¹⁰

Worsening of TSS is truncated at 150%.¹ From *New England Journal of Medicine*, Verstovsek S, Mesa RA, Gotlib J, et al, A double-blind, placebo-controlled trial of ruxolitinib for myelofibrosis, 366(9), 799-807. Copyright © 2012 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

Debilitating symptoms of MF^{1,10}

- Abdominal discomfort
- Pain under left ribs
- Night sweats
- Early satiety
- Pruritus
- Bone/muscle pain

* A secondary endpoint was the proportion of patients with a $\geq 50\%$ reduction in TSS from baseline to week 24 as measured by the daily patient diary, the modified Myelofibrosis Symptom Assessment Form. TSS encompasses core symptoms of MF: abdominal discomfort, early satiety, pain under left ribs, pruritus, night sweats, and bone/muscle pain. Symptom scores ranged from 0 to 10, with 0 representing symptoms "absent" and 10 representing symptoms "worst imaginable." These scores were added to create the daily total score, which has a maximum of 60. At baseline, mean TSS was 18.0 in the group receiving Jakafi and 16.5 in the group receiving placebo.^{1,10}

Risk of infection (continued)

- Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment
- 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. Monitor and treat patients with chronic HBV infection according to clinical guidelines

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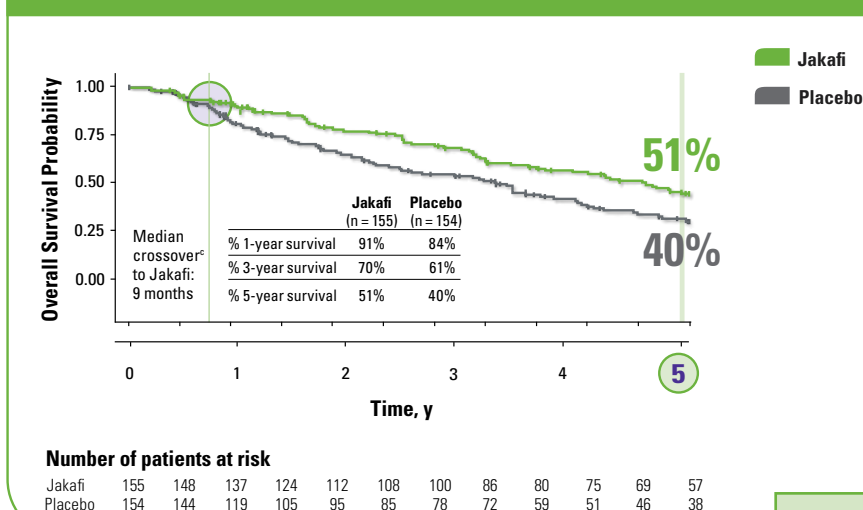


Jakafi® (ruxolitinib) 5-year overall survival data

COMFORT-I 5-year analysis: Jakafi and placebo

- At 3 years, survival probability was 70% for patients originally randomized to Jakafi and 61% for those originally randomized to placebo¹
- Overall survival was a prespecified secondary endpoint in COMFORT-I¹

Overall Survival Kaplan-Meier Curves by Treatment Group in COMFORT-I^{1,3,13,a,b}



^a The 5-year overall survival analysis is not included in the Full Prescribing Information for Jakafi. Although the 3-year overall survival analysis is presented in the Full Prescribing Information, P values and hazard ratios are omitted from the overall survival Kaplan-Meier curves.³

^b COMFORT-I was not designed to compare survival probabilities between Jakafi and placebo at 3 or 5 years.³

^c Patients randomized to placebo were eligible to cross over to receive Jakafi because of progression-driven events or at the physician's discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.³

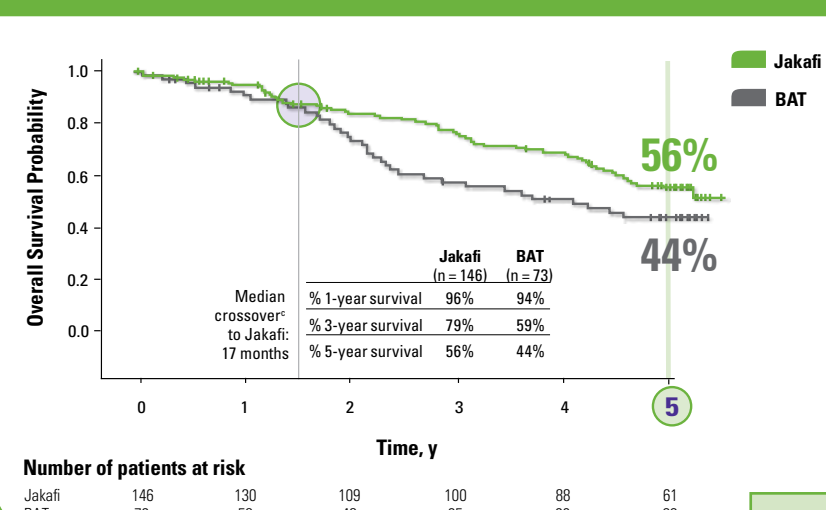
Jakafi 5-year overall survival probability was 51%³

All patients in the placebo group either crossed over to Jakafi at a median of 9 months or discontinued.¹

COMFORT-II 5-year analysis: Jakafi and best available therapy

- At 3 years, survival probability was 79% for patients originally randomized to Jakafi and 59% for those originally randomized to best available therapy¹
- Overall survival was a prespecified secondary endpoint in COMFORT-II¹

Overall Survival Kaplan-Meier Curves by Treatment Group in COMFORT-II^{1,14,a,b}



BAT, best available therapy.

^a The 5-year overall survival analysis is not included in the Full Prescribing Information for Jakafi. Although the 3-year overall survival analysis is presented in the Full Prescribing Information, P values and hazard ratios are omitted from the overall survival Kaplan-Meier curves.³

^b COMFORT-II was not designed to compare survival probabilities between Jakafi and best available therapy at 3 or 5 years.³

^c Patients randomized to best available therapy were eligible to cross over to receive Jakafi because of progression-driven events or at the physician's discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.³

Jakafi 5-year overall survival probability was 56%¹⁴

All patients in the best available therapy group either crossed over to Jakafi at a median of 17 months or discontinued.¹

Risk for symptom exacerbation following interruption or discontinuation of Jakafi

- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week
- After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi

Risk for symptom exacerbation following interruption or discontinuation of Jakafi (continued)

- Instruct patients not to interrupt or discontinue Jakafi without consulting their physician
- When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation

Please see related and other Important Safety Information on pages 12-13. Please click here for Full Prescribing Information.



Dose optimization is key to maintaining balance of safety and efficacy

Ensure your patients are receiving the appropriate dose of Jakafi

1 START: For adults with intermediate- or high-risk MF, the recommended starting doses are based on platelet counts¹

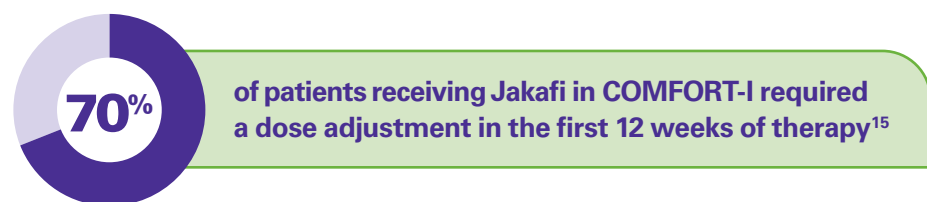
- A complete blood count (CBC) and platelet count must be performed before initiating Jakafi® (ruxolitinib)¹



Special populations: Please refer to the [Full Prescribing Information](#) for starting dose and other dose modifications, and when to avoid treatment in patients with renal or hepatic impairment and in those receiving concomitant strong CYP3A4 inhibitors or fluconazole.

2 MONITOR: Monitoring patients after initiation of Jakafi is essential, especially during the first 12 weeks of therapy

- A CBC and platelet count must be performed every 2 to 4 weeks until doses are stabilized, and then as clinically indicated. Doses may be titrated based on safety and efficacy¹



Monitoring blood counts and using appropriate dose management are essential to achieve desired efficacy and manage cytopenias¹

Risk for thrombocytopenia, anemia, and neutropenia

- Treatment with Jakafi can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. 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. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia ($ANC <0.5 \times 10^9/L$) was generally reversible by withholding Jakafi until recovery

3 OPTIMIZE: Individualize dosing of Jakafi to optimize balance between safety and efficacy¹

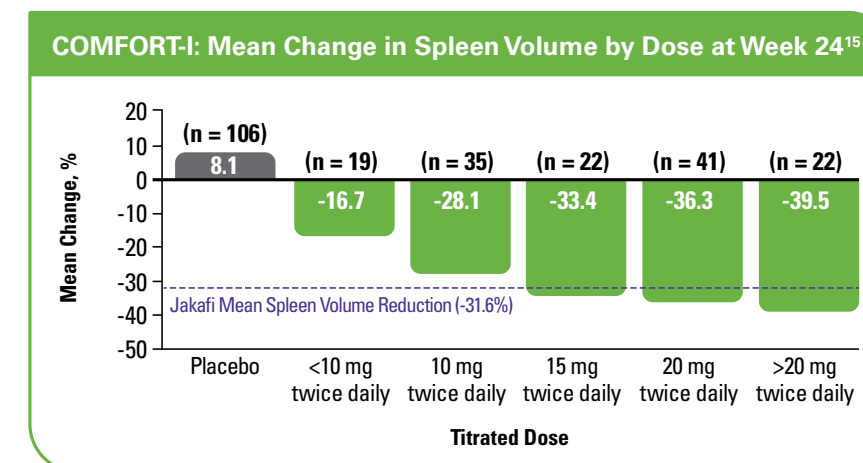
Managing anemia and thrombocytopenia

- In COMFORT-I, grades 3 and 4 thrombocytopenia or anemia occurred in 13% and 45% of patients receiving Jakafi, respectively. All grades of thrombocytopenia or anemia occurred in 70% and 96% of patients receiving Jakafi, respectively^{1,10}
- Dose modifications, temporarily withholding Jakafi, and/or transfusions may be required for patients developing anemia or thrombocytopenia¹
- Interrupt treatment for bleeding, neutropenia ($ANC <0.5 \times 10^9/L$), or thrombocytopenia (based on starting platelet count)¹

<1% of patients receiving Jakafi in the COMFORT studies discontinued due to anemia or thrombocytopenia¹

Dose may be increased in the case of an insufficient response¹

Efficacy based on titrated dose



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- Doses may be increased if the response is insufficient and platelet, hemoglobin, and neutrophil counts are adequate and treatment has not been reduced or interrupted in the prior 4 weeks¹
- Doses should not be increased during the first 4 weeks of therapy and not more frequently than every 2 weeks¹
- Discontinue Jakafi if there is no spleen size reduction or symptom improvement after 6 months of therapy¹

Please see related and other Important Safety Information on pages 12-13. Please click here for Full Prescribing Information complete dosing recommendations.



Jakafi[®] (ruxolitinib) adverse reactions

COMFORT-I hematologic adverse reactions^{1,10}

Hematologic Adverse Reactions	Jakafi (n = 155)		Placebo (n = 151)	
	All Grades, %	Grades 3 and 4, %	All Grades, %	Grades 3 and 4, %
Anemia	96	45	87	19
Thrombocytopenia	70	13	31	1
Neutropenia	19	7	4	2

- The most frequently observed reactions were thrombocytopenia and anemia¹
- Perform a pre-treatment CBC, and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated¹

COMFORT-I and COMFORT-II discontinuation rates^{1,3}

Hematologic Abnormality	Discontinuation Rate, ³ %	Management ¹
Thrombocytopenia	0.7	Managed by reducing the dose or temporarily interrupting Jakafi; if clinically indicated, platelet transfusions may be administered
Anemia	0.3	Some patients may require blood transfusions and/or dose modifications of Jakafi
Neutropenia	0.3	Generally reversible; temporarily withhold Jakafi until recovery

- At week 24, the discontinuation rates for adverse reactions, regardless of causality, were 11% in patients receiving Jakafi and 11% in patients receiving placebo^{1,10}
- In COMFORT-I, 70% of patients required a dose adjustment in the first 12 weeks of therapy, and 2% of patients discontinued therapy because of hematologic adverse reactions at week 24^{3,15}
- <1% of patients receiving Jakafi in the COMFORT studies discontinued due to anemia or thrombocytopenia¹

In COMFORT-I:

- 60% of patients treated with Jakafi and 38% of patients receiving placebo had red blood cell transfusions during randomized treatment¹
- 123 of 155 patients in the group receiving Jakafi were transfusion independent at baseline, compared with 119 of 151 patients in the group receiving placebo. Of the 123 transfusion-independent patients in the group receiving Jakafi, 27% became transfusion dependent* during the 8 weeks before data cutoff, compared with 14.4% of patients in the group receiving placebo³

* New-onset transfusion dependency: The use of 2 or more units of red blood cell product(s) during the final 8 weeks before database lock in a patient who was not transfusion dependent at baseline.¹⁰

COMFORT-I nonhematologic adverse reactions^{1,3}

Nonhematologic Adverse Reactions	Jakafi (n = 155)		Placebo (n = 151)	
	All Grades, %	Grades 3 and 4, %	All Grades, %	Grades 3 and 4, %
Bruising	23	<1	15	0
Dizziness	18	<1	7	0
Headache	15	0	5	0
Urinary tract infection	9	0	5	1
Weight gain	7	<1	1	<1
Flatulence	5	0	<1	0
Herpes zoster	2	0	<1	0
Additional Nonhematologic Abnormalities	Jakafi		Placebo	
	All Grades, ^a %	Grades 3 and 4, %	All Grades, ^a %	Grades 3 and 4, %
ALT	27	1	8	0
AST	18	0	7	0
Cholesterol elevation	17	0	<1	0

ALT, alanine transaminase; AST, aspartate transaminase.

^a These lab values represent "new or worsening."

Other important safety considerations

- Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations
- Treatment with Jakafi has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiating Jakafi. Monitor and treat according to clinical guidelines for the management of hyperlipidemia
- In myelofibrosis and polycythemia vera, the most common nonhematologic adverse reactions (incidence ≥15%) were bruising, dizziness, headache, and diarrhea. In acute graft-versus-host disease, the most common nonhematologic adverse reactions (incidence >50%) were infections and edema

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Important Safety Information

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. 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. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia (ANC $<0.5 \times 10^9/L$) was generally reversible by withholding Jakafi until recovery
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, 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 Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination
- Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment
- 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. Monitor and treat patients with chronic HBV infection according to clinical guidelines

Important Safety Information (continued)

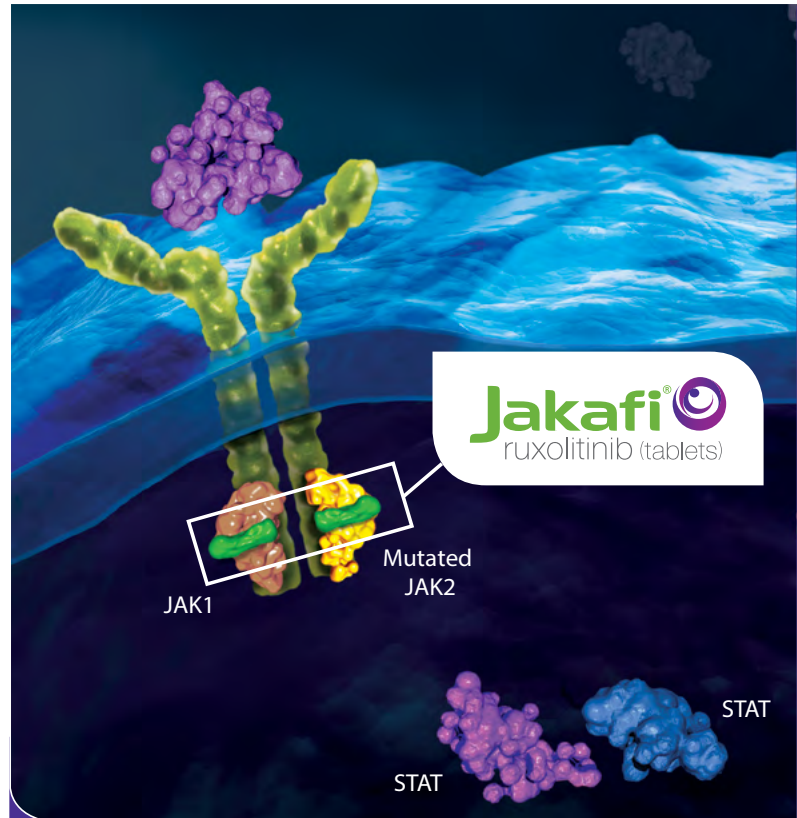
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation
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- Dose modifications may be required when administering Jakafi with strong CYP3A4 inhibitors or fluconazole or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breastfeed during treatment and for 2 weeks after the final dose

Please [click here](#) for Full Prescribing Information.



Jakafi® (ruxolitinib) is a potent and highly selective JAK1 and JAK2 inhibitor¹⁶

Jakafi targets a primary driver of MF¹



JAK1
Plays major role in signaling of key proinflammatory cytokines¹⁶

JAK2
Mediates signals for hematopoietic growth factors¹⁶

Jakafi®
ruxolitinib (tablets)

JAK1 Mutated JAK2 STAT STAT

Jakafi can be used for appropriate patients regardless of JAK2 mutation status^{16,17}

JAK, Janus-associated kinase; STAT, signal transducer and activator of transcription.

Other important safety considerations

- Dose modifications may be required when administering Jakafi with strong CYP3A4 inhibitors or fluconazole or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy
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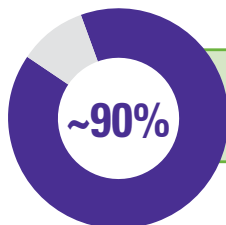
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References: 1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation. 2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myeloproliferative Neoplasms V.1.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed September 4, 2019. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 3. Data on file. Incyte Corporation. Wilmington, DE. 4. Barbui T, Barosi G, Birgegard G, et al. Philadelphia-negative classical myeloproliferative neoplasms: critical concepts and management recommendations from European LeukemiaNet. *J Clin Oncol*. 2011;29(6):761-770. 5. Gangat N, Caramazza D, Vaidya R, et al. DIPSS plus: a refined Dynamic International Prognostic Scoring System for primary myelofibrosis that incorporates prognostic information from karyotype, platelet count, and transfusion status. *J Clin Oncol*. 2011;29(4):392-397. 6. Cervantes F, Dupriez B, Pereira A, et al. New prognostic scoring system for primary myelofibrosis based on a study of the International Working Group for Myelofibrosis Research and Treatment. *Blood*. 2009;113(13):2895-2901. 7. Tefferi A, Cervantes F, Mesa R, et al. Revised response criteria for myelofibrosis: International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report. *Blood*. 2013;122(8):1395-1398. 8. Vannucchi AM, Kantarjian HM, Kiladjian J-J, et al; on behalf of the COMFORT Investigators. A pooled analysis of overall survival in COMFORT-I and COMFORT-II, 2 randomized phase III trials of ruxolitinib for the treatment of myelofibrosis. *Haematologica*. 2015;100(9):1139-1145. 9. Tremblay D, Schwartz M, Bakst R, et al. Modern management of splenomegaly in patients with myelofibrosis. *Ann Hematol*. 2020. doi.org/10.1007/s 00277-020-04069-4 10. Verstovsek S, Mesa RA, Gotlib J, et al. A double-blind, placebo-controlled trial of ruxolitinib for myelofibrosis. *N Engl J Med*. 2012;366(9):799-807. 11. Harrison C, Kiladjian J-J, Al-Ali HK, et al. JAK inhibition with ruxolitinib versus best available therapy for myelofibrosis. *N Engl J Med*. 2012;366(9):787-798. 12. Deisseroth A, Kaminskas E, Grillo J, et al. US Food and Drug Administration approval: ruxolitinib for the treatment of patients with intermediate and high-risk myelofibrosis. *Clin Cancer Res*. 2012;18(12):3212-3217. 13. Verstovsek S, Mesa RA, Gotlib J, et al; for COMFORT-I investigators. Long-term treatment with ruxolitinib for patients with myelofibrosis: 5-year update from the randomized, double-blind, placebo-controlled, phase 3 COMFORT-I trial. *J Hematol Oncol*. 2017;10(1):55. 14. Harrison CN, Vannucchi AM, Kiladjian J-J, et al; on behalf of COMFORT-II investigators. Long-term findings from COMFORT-II, a phase 3 study of ruxolitinib vs best available therapy for myelofibrosis. *Leukemia*. 2016;30(8):1701-1707. 15. Verstovsek S, Mesa RA, Gotlib J, et al. Efficacy, safety and survival with ruxolitinib in patients with myelofibrosis: results of a median 2-year follow-up of COMFORT-I. *Haematologica*. 2013;98(12):1865-1871. 16. Quintás-Cardama A, Vaddi K, Liu P, et al. Preclinical characterization of the selective JAK1/2 inhibitor INCB018424: therapeutic implications for the treatment of myeloproliferative neoplasms. *Blood*. 2010;115(15):3109-3117. 17. Verstovsek S, Kantarjian H, Mesa RA, et al. Safety and efficacy of INCB018424, a JAK1 and JAK2 inhibitor, in myelofibrosis. *N Engl J Med*. 2010;363(12):1117-1127.

For adults with intermediate- or high-risk MF¹

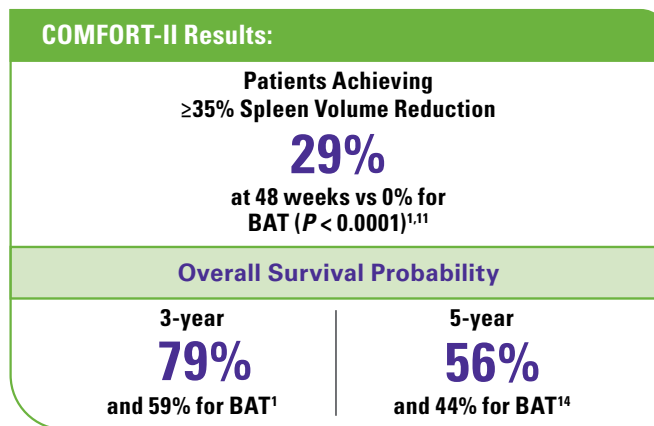
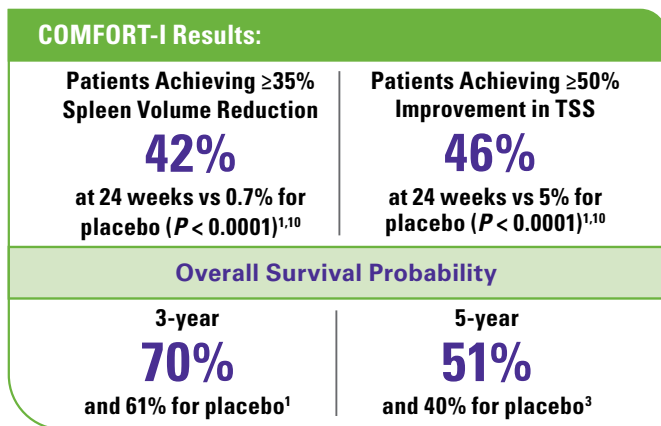
Intervene with Jakafi[®] (ruxolitinib) at diagnosis

MF is a serious disease that may require active management at diagnosis⁴



of patients with primary MF may be appropriate for treatment with Jakafi^{1,5*}

* Based on a study of patients with primary MF, approximately 90% (375/428) of evaluable patients were considered to be intermediate or high risk within 1 year of diagnosis.⁵



BAT, best available therapy; TSS, Total Symptom Score.

Actively manage your patients' disease at diagnosis

Indications and Usage

Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults.

Important safety considerations

- Treatment with Jakafi can cause 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. In patients with cytopenias, consider dose reductions or temporarily withholding Jakafi or transfusions, as clinically indicated
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Evaluate patients prior to and while receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines

Please see related and other Important Safety Information on pages 12-13. Please [click here](#) for Full Prescribing Information.

hcp.jakafi.com

Experience with Jakafi since FDA approval^{3†}



[†] Estimated total patients treated with commercially available Jakafi in the United States since 2011.³
See Full Prescribing Information for FDA-approved indications.



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Jakafi[®]
ruxolitinib (tablets)