Monitor patients with myelofibrosis to find their optimal JAKAVI® (ruxolitinib) dose[1]

This material was created and funded by Novartis. This promotional material is intended for UK healthcare professionals only. For further information on the adverse events and special warnings for JAKAVI®, please refer to the SmPC.

JAKAVI® is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. JAKAVI® is also indicated for adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.[1]

Reference: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com or call 01276 698370.

Please scan the QR code or tap below for the **JAKAVI® Prescribing Information**

UK | FA-11346940-1 | August 2025

NOVARTIS

JAKAVI® ruxolitinib

Pre-initiation/ Initiation | Approximately 4 weeks | Approximately 8 weeks | Approximately 8–12 weeks | 24 weeks

Pre-initiation[1]

A complete blood cell count, including a white blood cell count differential, must be performed before initiating therapy with **JAKAVI®**.

Starting dose[1,2]

Based on platelet count:

>200,000/mm^3 – 20 mg twice daily.

100,000–200,000/mm^3 – 15 mg twice daily.

75,000–<100,000/mm^3 – 10 mg twice daily.

50,000–<75,000/mm^3 – 5 mg twice daily.

Special populations such as those with severe renal impairment, end stage renal disease and hepatic impairment require adjusted starting and maintenance doses. Please refer to section 4.2 of the SmPC for full information.

Monitoring[1]

Complete blood count, including a white blood cell count differential, should be monitored **every 2 to 4 weeks** until dose is stabilised, then as clinically indicated.

Proactively monitor all patients' myelofibrosis-related symptoms to treat as early as possible in those who are eligible for JAKAVI® and adjust dose as needed based on efficacy and safety.[1,3–6]

Special populations

Treatment may continue as long as benefit–risk balance remains positive. After interruption or discontinuation of JAKAVI® dosing, symptoms of myelofibrosis may return over a period of approximately 1 week. Unless abrupt discontinuation is required, gradual tapering of the dose may be considered, although the utility of tapering is unproven.

SmPC, Summary of Product Characteristics.

References: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics. **2.** Harrison C, et al. N Engl J Med. 2012;366:787–798. **3.** Mesa R, et al. Blood. 2012;120:1727. **4.** McLornan DP, et al. Br J Haematol. 2024;204:136–150. **5.** NICE. Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis. TA386, 2016. Available at: https://www.nice.org.uk/guidance/ta386. Last accessed August 2025. **6.** Scottish Medicines Consortium. Available at: https://www.scottishmedicines.org.uk/medicines-advice/ruxolitinib-jakavi-fullsubmission-86713/. Last accessed August 2025.

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Special populations

Renal impairment[1]

Discontinue JAKAVI® after 6 months if there is no spleen size reduction or symptom improvement.

Treatment of MF and PV may be continued as long as the benefit-risk remains positive. However, the treatment should be discontinued after 6 months if there has been no reduction in spleen size or improvement in symptoms since initiation of therapy.

It is recommended that, for patients who have demonstrated some degree of clinical improvement, JAKAVI® therapy be discontinued if they sustain an increase in their spleen length of 40% compared with baseline size (roughly equivalent to a 25% increase in spleen volume) and no longer have tangible improvement in disease-related symptoms.[1]

Hepatic impairment[1]

In MF patients with any hepatic impairment, the recommended starting dose based on platelet count should be reduced by approximately 50% to be administered twice daily. Subsequent doses should be adjusted based on careful monitoring of safety and efficacy.

Elderly patients (≥65 years)[1]

No additional dose adjustments are recommended for elderly patients.

Paediatric population[1]

The safety and efficacy of JAKAVI® in children and adolescents aged up to 18 years with MF and PV have not been established. No data are available (see section 5.1).

MF, myelofibrosis; PV, polycythaemia vera.

Reference: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI ® summary of product characteristics.

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Improvement in spleen size[1,2]

Reduction in palpable spleen length may be **observed by Week 4**.

Reduction in spleen size may be observed later than Week 4 throughout the course of treatment.

Dose titration[1]

The starting dose should not be increased during the **first 4 weeks** of therapy.

Doses should not be increased more frequently than at **2-week intervals**.

Dose should be titrated based on efficacy and tolerability, per SmPC.

Proactively monitor all patients' myelofibrosis-related symptoms to treat as early as possible in those who are eligible for JAKAVI® and adjust dose as needed based on efficacy and safety.[1,3–6]

Treatment may continue as long as benefit–risk balance remains positive. After interruption or discontinuation of JAKAVI® dosing, symptoms of myelofibrosis may return over a period of approximately 1 week. Unless abrupt discontinuation is required, gradual tapering of the dose may be considered, although the utility of tapering is unproven.

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Thrombocytopenia[1]

In Phase 3 clinical studies, median onset of Grade 3 or 4 thrombocytopenia was **8 weeks**.*

Management: Interrupt treatment if platelet count <50,000/mm^3 or absolute neutrophil count reduced to <500/mm^3.

Thrombocytopenia is generally reversible and is usually managed by reducing the dose or temporarily withholding **JAKAVI®**. However, platelet transfusions may be required as clinically indicated. After recovery of blood counts above these levels, dosing may be re-started at 5 mg twice daily and gradually increased based on careful monitoring of complete blood cell count, including a white blood cell count differential.

Please refer to the dosing recommendation in section 4.2 of the SmPC for information on specific dose reductions in patients with thrombocytopenia.

Symptom improvement[1–3]

In patients with symptom improvement, symptom responses generally occurred rapidly – **usually within the first 8 weeks.**

Treatment should be discontinued if absolute neutrophil counts are less than 500/mm^3.[1]

Anaemia[1,4,5]

Anaemia was generally transient, reaching a nadir of approximately 10 g/L below baseline after **8 to 12 weeks** of therapy and gradually recovering to reach a new steady state (approximately 5 g/L below baseline) by Week 24.

Management: Patients with anaemia may require blood transfusions.

Dose modifications or interruption for patients developing anaemia may also be considered.

Proactively monitor all patients' myelofibrosis-related symptoms to treat as early as possible in those who are eligible for JAKAVI® and adjust dose as needed based on efficacy and safety.[1,5–8]

* Grade 3 or 4 thrombocytopenia is defined as absolute platelet counts below 50,000/mm^3.[1]

Treatment may continue as long as benefit–risk balance remains positive. After interruption or discontinuation of JAKAVI® dosing, symptoms of myelofibrosis may return over a period of approximately 1 week. Unless abrupt discontinuation is required, gradual tapering of the dose may be considered, although the utility of tapering is unproven.

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Efficacy[1]

Discontinue **JAKAVI®** after 6 months if there is no spleen size reduction or symptom improvement.

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It is recommended that, for patients who have demonstrated some degree of clinical improvement, **JAKAVI®** therapy be discontinued if they sustain an increase in their spleen length of 40% compared with baseline size (roughly equivalent to a 25% increase in spleen volume) and no longer have tangible improvement in disease-related symptoms.[1]

Proactively monitor all patients' myelofibrosis-related symptoms to treat as early as possible in those who are eligible for JAKAVI® and adjust dose as needed based on efficacy and safety.[1–5]

Treatment may continue as long as benefit–risk balance remains positive. After interruption or discontinuation of JAKAVI® dosing, symptoms of myelofibrosis may return over a period of approximately 1 week. Unless abrupt discontinuation is required, gradual tapering of the dose may be considered, although the utility of tapering is unproven.

MF, myelofibrosis; PV, polycythaemia vera.

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