

OJJAARA (mometotinib) DOSING GUIDE



One pill, once daily
for patients who have
myelofibrosis (MF)
with anemia

Ojjaara
(mometotinib)
200 mg • 150 mg • 100 mg tablets

INDICATION

OJJAARA is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

IMPORTANT SAFETY INFORMATION

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Please see additional Important Safety Information throughout and on pages 6-8 and accompanying full Prescribing Information.

One pill, once daily for patients who have MF with anemia¹

- The recommended dosage of OJJAARA is **200 mg orally once daily**
- OJJAARA may be **taken with or without food**
- Swallow OJJAARA tablets whole. Do not cut, crush, or chew tablets
- If a dose of OJJAARA is missed, the next scheduled dose should be taken the following day

Laboratory monitoring for safety

- Obtain the following blood tests prior to starting treatment with OJJAARA, periodically during treatment, and as clinically indicated:
 - Complete blood count (CBC) with platelets
 - Hepatic panel

See pages 4 and 5 for information on dosage modifications due to hepatic impairment and adverse reactions.

OJJAARA is available in 3 dosage strengths:



Not actual size of the OJJAARA tablets.

IMPORTANT SAFETY INFORMATION (cont'd)

Hepatotoxicity

- Two of the 993 patients with MF who received at least one dose of OJJAARA in clinical trials experienced reversible drug-induced liver injury. Overall, new or worsening elevations of ALT and AST (all grades) occurred in 23% and 24%, respectively, of patients treated with OJJAARA; Grade 3 and 4 transaminase elevations occurred in 1% and 0.5% of patients, respectively. New or worsening elevations of total bilirubin occurred in 16% of patients treated with OJJAARA. All total bilirubin elevations were Grades 1-2. The median time to onset of any grade transaminase elevation was 2 months, with 75% of cases occurring within 4 months.

Additional Information on Dosing From Clinical Trials With OJJAARA¹

In SIMPLIFY-1, patients were eligible to switch to open-label OJJAARA after 24 weeks (without tapering of the Janus kinase inhibitor received during the randomization period).

Drug interactions¹

- **Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors:** Momelotinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases momelotinib maximal concentrations (C_{max}) and area under the concentration-time curve (AUC), which may increase the risk of adverse reactions with OJJAARA. Monitor patients concomitantly receiving an OATP1B1/B3 inhibitor for adverse reactions and consider OJJAARA dose modifications
- **Breast Cancer Resistance Protein (BCRP) Substrates:** Momelotinib is a BCRP inhibitor. OJJAARA may increase exposure of BCRP substrates, which may increase the risk of BCRP substrate adverse reactions. When administered concomitantly with OJJAARA, initiate rosuvastatin (BCRP substrate) at 5 mg and do not increase to more than 10 mg once daily. Dose adjustment of other BCRP substrates may also be needed. Follow approved product information recommendations for other BCRP substrates

IMPORTANT SAFETY INFORMATION (cont'd)

Hepatotoxicity (cont'd)

- Delay starting therapy in patients presenting with uncontrolled acute and chronic liver disease until apparent causes have been investigated and treated as clinically indicated. When initiating OJJAARA, refer to dosing in patients with hepatic impairment.
- Monitor liver tests at baseline, every month for 6 months during treatment, then periodically as clinically indicated. If increases in ALT, AST or bilirubin related to treatment are suspected, modify OJJAARA dosage based upon Table 1 within the Prescribing Information.

Please see additional Important Safety Information throughout and on pages 6-8 and accompanying full Prescribing Information.

Dosage modifications



Dosage modification for hepatic impairment

The recommended starting dosage in patients with severe hepatic impairment (Child-Pugh Class C) is 150 mg orally once daily. No dose adjustment is recommended for patients with mild or moderate hepatic impairment.

Dosage modification for adverse reactions

Manage hematologic and non-hematologic adverse reactions as described in the following table.

Thrombocytopenia

Baseline Platelet Count	Platelet Count	Dose Modification*
≥100 × 10 ⁹ /L	20 × 10 ⁹ /L to <50 × 10 ⁹ /L	• Reduce daily dose by 50 mg from the last given dose
	<20 × 10 ⁹ /L	• Interrupt treatment until platelets recover to 50 × 10 ⁹ /L • Restart OJJAARA at a daily dose of 50 mg below the last given dose [†]
≥50 × 10 ⁹ /L to <100 × 10 ⁹ /L	<20 × 10 ⁹ /L	• Interrupt treatment until platelets recover to 50 × 10 ⁹ /L • Restart OJJAARA at a daily dose of 50 mg below the last given dose [†]
<50 × 10 ⁹ /L	<20 × 10 ⁹ /L	• Interrupt treatment until platelets recover to baseline • Restart OJJAARA at a daily dose of 50 mg below the last given dose [†]

Neutropenia

Absolute Neutrophil Count (ANC)	Dose Modification*
<0.5 × 10 ⁹ /L	• Interrupt treatment until ANC ≥0.75 × 10 ⁹ /L • Restart OJJAARA at a daily dose of 50 mg below the last given dose [†]

Hepatotoxicity (unless other apparent causes)

	Dose Modification*
ALT and/or AST >5 × ULN (or >5 × baseline, if baseline is abnormal) and/or total bilirubin [‡] >2 × ULN (or >2 × baseline, if baseline is abnormal)	• Interrupt treatment until AST and ALT ≤2 × ULN or baseline [‡] and total bilirubin ≤1.5 × ULN or baseline [§] • Restart OJJAARA at a daily dose of 50 mg below the last given dose [†] • If reoccurrence of ALT or AST elevations >5 × ULN, permanently discontinue OJJAARA

Other Non-Hematologic

	Dose Modification*
Grade 3 or higher	• Interrupt treatment until the toxicity resolves to Grade 1 or lower (or baseline) • Restart OJJAARA at a daily dose of 50 mg below the last given dose [†]

ALT=alanine transaminase; AST=aspartate transaminase; ULN=upper limit of normal.

*Reinitiate or escalate treatment up to starting dosage as clinically appropriate.

[†]May reinitiate treatment at 100 mg if previously dosed at 100 mg.

[‡]If baseline >2 × ULN.

[§]If baseline >1.5 × ULN.

^{||}Graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE).



Discontinue OJJAARA in patients unable to tolerate 100 mg once daily¹

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IMPORTANT SAFETY INFORMATION

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Hepatitis B Reactivation

- Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine transaminase (ALT) or aspartate transaminase (AST), have been reported in patients with chronic hepatitis B virus (HBV) infection taking Janus Kinase (JAK) inhibitors, including OJJAARA. The effect of OJJAARA on viral replication in patients with chronic HBV infection is unknown. In patients with HBV infections, check hepatitis B serologies prior to starting OJJAARA. If HBsAg and/or anti-HBc antibody is positive, consider consultation with a hepatologist regarding monitoring for reactivation versus prophylactic hepatitis B therapy. Patients with chronic HBV infection who receive OJJAARA should have their chronic HBV infection treated and monitored according to clinical HBV guidelines.

Thrombocytopenia and Neutropenia

- New or worsening thrombocytopenia, with platelet count less than $50 \times 10^9/L$, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than $50 \times 10^9/L$.
- Severe neutropenia, absolute neutrophil count (ANC) less than $0.5 \times 10^9/L$, was observed in 2% of patients treated with OJJAARA.
- Assess complete blood counts (CBC), including platelet and neutrophil counts, before initiating treatment and periodically during treatment as clinically indicated. Interrupt dosing or reduce the dose for thrombocytopenia or neutropenia.

Hepatotoxicity

- Two of the 993 patients with MF who received at least one dose of OJJAARA in clinical trials experienced reversible drug-induced liver injury. Overall, new or worsening elevations of ALT and AST (all grades) occurred in 23% and 24%, respectively, of patients treated with OJJAARA; Grade 3 and 4 transaminase elevations occurred in 1% and 0.5% of patients, respectively. New or worsening elevations of total bilirubin occurred in 16% of patients treated with OJJAARA. All total bilirubin elevations were Grades 1-2. The median time to onset of any grade transaminase elevation was 2 months, with 75% of cases occurring within 4 months.
- Delay starting therapy in patients presenting with uncontrolled acute and chronic liver disease until apparent causes have been investigated and treated as clinically indicated. When initiating OJJAARA, refer to dosing in patients with hepatic impairment.

- Monitor liver tests at baseline, every month for 6 months during treatment, then periodically as clinically indicated. If increases in ALT, AST or bilirubin related to treatment are suspected, modify OJJAARA dosage based upon Table 1 within the Prescribing Information.

Major Adverse Cardiovascular Events (MACE)

- Another JAK inhibitor increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke [compared with those treated with tumor necrosis factor (TNF) blockers] in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients receiving OJJAARA of the symptoms of serious cardiovascular events and the steps to take if they occur.

Thrombosis

- Another JAK inhibitor increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Evaluate patients with symptoms of thrombosis and treat appropriately.

Malignancies

- Another JAK inhibitor increased the risk of lymphoma and other malignancies excluding nonmelanoma skin cancer (NMSC) (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Current or past smokers were at increased risk.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

Adverse Reactions

- The most common adverse reactions ($\geq 20\%$ in either study) are thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors

- Mometinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases momelotinib maximal concentrations (C_{max}) and area under the concentration-time curve (AUC), which may increase the risk of adverse reactions with OJJAARA. Monitor patients concomitantly receiving an OATP1B1/B3 inhibitor for adverse reactions and consider OJJAARA dose modifications.

Please see additional Important Safety Information continued on back cover and accompanying full Prescribing Information.

Ojjaara
(mometinib)

IMPORTANT SAFETY INFORMATION (cont'd)

Breast Cancer Resistance Protein (BCRP) Substrates

- Momelotinib is a BCRP inhibitor. OJJAARA may increase exposure of BCRP substrates, which may increase the risk of BCRP substrate adverse reactions. When administered concomitantly with OJJAARA, initiate rosuvastatin (BCRP substrate) at 5 mg and do not increase to more than 10 mg once daily. Dose adjustment of other BCRP substrates may also be needed. Follow approved product information recommendations for other BCRP substrates.

Pregnancy

- Available data in pregnant women are insufficient. OJJAARA should only be used during pregnancy if the expected benefits to the mother outweigh the potential risks to the fetus.

Lactation

- It is not known whether OJJAARA is excreted in human milk. Because of the potential for serious adverse reactions in a breastfed child, patients should not breastfeed during treatment with OJJAARA, and for at least 1 week after the last dose of OJJAARA.

Females and Males of Reproductive Potential

- Advise females of reproductive potential who are not pregnant to use highly effective contraception during therapy and for at least 1 week after the last dose of OJJAARA.

Hepatic Impairment

- Momelotinib exposure increased with severe hepatic impairment (Child-Pugh C). The recommended starting dose of OJJAARA in patients with severe hepatic impairment (Child-Pugh C) is 150 mg orally once daily. No dose modification is recommended for patients with mild hepatic impairment (Child-Pugh A) or moderate hepatic impairment (Child-Pugh B).

Please see accompanying full Prescribing Information.

Reference: 1. OJJAARA (momelotinib). Prescribing Information. GSK; 2023.



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