OJJAARA (momelotinib) DOSING GUIDE

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

Ojjaara (momelotinib)
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.

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.

Please see additional Important Safety Information on pages 4-5 and accompanying full Prescribing Information.

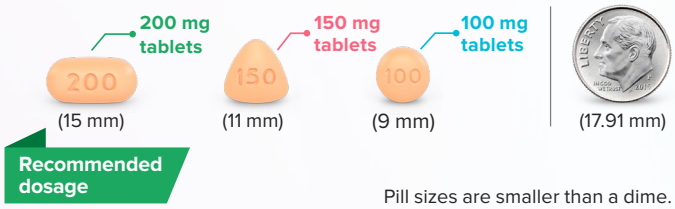
Once-daily OJJAARA: an oral therapy for patients who have myelofibrosis with anemia[1]

- 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[1]

- 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

OJJAARA is available in 3 dosage strengths[1,2]:



Pill sizes are smaller than a dime.

Drug interactions[1]

- **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

See next page for information on dosage modifications due to hepatic impairment and adverse reactions.

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.
- 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 on pages 4-5 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Dosage modifications[1]

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.

For adverse reactions

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

Thrombocytopenia – Baseline Platelet Count ≥100 × 10^9/L*			
	Dose at Time of Platelet Decline		
	200 mg	150 mg	100 mg
Current Platelet Count (× 10^9/L)	**New recommended dose***		
20 × 10^9/L to <50 × 10^9/L	150 mg	100 mg	Discontinue
<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†		
Thrombocytopenia – Baseline Platelet Count ≥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†		
Thrombocytopenia – Baseline Platelet Count <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) <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 recurrence 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 daily

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Thrombocytopenia and Neutropenia

- New or worsening thrombocytopenia, with platelet count less than 50×10^9/L, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than 50×10^9/L.
- Severe neutropenia, absolute neutrophil count (ANC) less than 0.5×10^9/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

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- 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.

Severe Cutaneous Adverse Reactions (SCARs)

- Severe cutaneous adverse reactions (SCARs), including toxic epidermal necrolysis (TEN), have been observed in some patients treated with OJJAARA.
- If signs or symptoms of SCARs occur, interrupt OJJAARA until the etiology of the reaction has been determined. Consider early consultation with a dermatologist for evaluation and management.
- If etiology is considered to be associated with OJJAARA, permanently discontinue OJJAARA and do not reintroduce OJJAARA in patients who have experienced SCARs or other life-threatening cutaneous reactions during treatment with OJJAARA.

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.

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

Symptom Exacerbation Following Interruption or Discontinuation of Treatment

- Following discontinuation of JAK inhibitors, including OJJAARA, signs and symptoms from myeloproliferative neoplasms may flare. Some patients with MF have experienced one or more of the following after discontinuing JAK inhibitors: fever, respiratory distress, hypotension, disseminated intravascular coagulation, or multi-organ failure.
- If one or more of these signs and symptoms occur after discontinuation of OJJAARA, evaluate for and treat any intercurrent illness and consider restarting OJJAARA. Instruct patients not to interrupt or discontinue therapy without consulting their healthcare provider. When discontinuing or interrupting therapy for reasons other than potentially life-threatening toxicities, consider tapering the dose of OJJAARA gradually rather than discontinuing abruptly.

Adverse Reactions

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

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- 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 full Prescribing Information, including Patient Information, for OJJAARA.

References: 1. OJJAARA (momelotinib). Prescribing Information. GSK; 2026. **2.** Data on file, GSK.

Ojjaara (momelotinib)

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