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

ADDING OJJAARA (MOMELOTINIB) TO AN EPIC EHR PROTOCOL FOR APPROPRIATE PATIENTS WHO HAVE INTERMEDIATE TO HIGH-RISK MYELOFIBROSIS WITH ANEMIA

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 the Indication and Important Safety Information on pages 7-9.
Click here for accompanying full Prescribing Information.

EHR=electronic health record.

ABOUT THIS GUIDE

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This guide provides educational information to help healthcare providers who want to create Protocols that include OJJAARA or want to add OJJAARA to an existing Protocol. Protocols group order sets for medications, lab testing, procedures, and other aspects of care based on the patient's diagnosis and condition. It is important to evaluate oncology protocols frequently as treatment options, such as OJJAARA, become available.

This guide does not constitute guidance for treatment or medical advice. It is the responsibility of the healthcare provider to select a treatment based on their independent medical judgment and the needs of each individual patient.

The examples and instructions listed in this guide are based on the 2022 and later versions of Epic. Locations, illustrations, and terminology are subject to change with system updates. This guide is meant to serve as an overview only and should not replace detailed instructions provided to you by your internal or external EHR support resources. GSK makes no claims or warranties about the applicability or appropriateness of this information. This guide has not been reviewed or endorsed by Epic. GSK does not endorse or recommend any EHR system.

ROLE OF PROTOCOLS OR TREATMENT PLANS

Protocols, also known as Treatment Plans to the clinical staff, are commonly used to help facilitate the care of patients. Protocols and their related Order Groups help enable consistency of care and streamline ordering of an entire regimen including specific care instructions.

As treatment options such as OJJAARA become available, it may be necessary to create an additional Protocol or to update an existing Protocol to remove system obstacles to prescribe OJJAARA for its approved indication. Updating relevant Protocols to include OJJAARA communicates to the care team that it is available for appropriate patients.

Refreshing protocols is a common process and provides an opportunity to incorporate treatment updates and guideline changes. Protocols are typically updated at the health system level to help reduce practice variation. Typically, an oncology practice will conduct a clinical review process to confirm and approve a suggested Protocol update. Various stakeholders may participate in reviewing Protocol modification requests prior to the approval.

Creating or Editing a Protocol

Upon request and approval from the Clinical Team, the Health System IT Team creates protocols that include the necessary orders for a given course of treatment.

When an HCP assigns a protocol to a patient, it becomes the patient's Treatment Plan.

As a prerequisite inclusion in a Protocol, Treatment Plan, or Order Group, OJJAARA must exist as an orderable item. It may be appropriate to validate that all treatments are appropriately set up as orderable items prior to beginning the setup of Order Groups.

Note: If OJJAARA is not available for selection in Epic, the practice may need to run a drug database update. As a backup option, the practice EHR Support/ IT team may be able to manually add OJJAARA, subject to the practice's business rules for drug database maintenance.

Please see the **Indication** and **Important Safety Information** on pages 7-9.
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How to Set Up a New Order Group for OJJAARA in Epic

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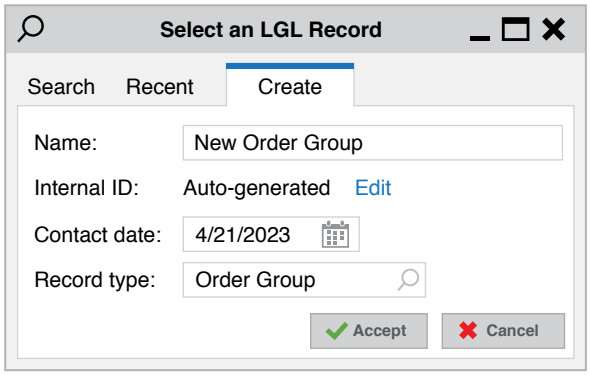
The first step in the process of setting up a Protocol for OJJAARA is to create an Order Group. After you create the Order Group, you can add it to the Protocol.

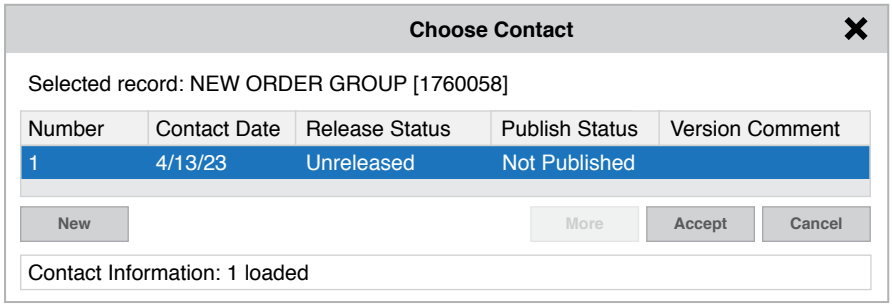
Create a New Order Group

1. Navigate to **Beacon Admin**, select the **Order Group Builder**.
2. Select the **Create** tab.

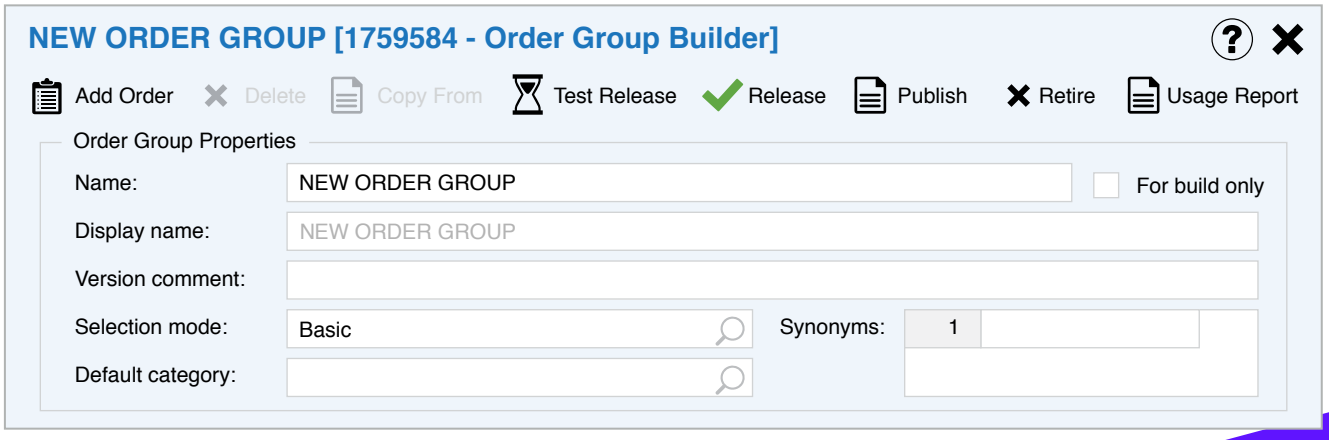


Example of Order Group creation

3. Enter the **Name** of the Order Group to be set up. For example, **OJJAARA**.
4. Select **Accept** on the initial contact date to open the **Order Group Builder** window.
5. Populate appropriate **Order Group Properties**. Enter a **Default category**. Add **Synonyms** to help when searching for Order Groups.



Example of initiating a new Order Group



Example of the Order Group Builder window

Please see the Indication and Important Safety Information on pages 7-9.
Click here for accompanying full Prescribing Information.

How to Set Up a New Order Group for OJJAARA in Epic (cont'd)

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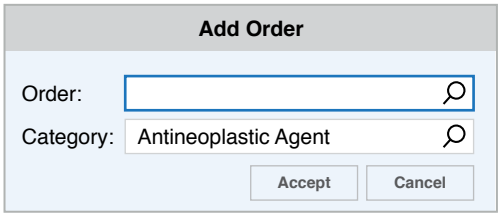
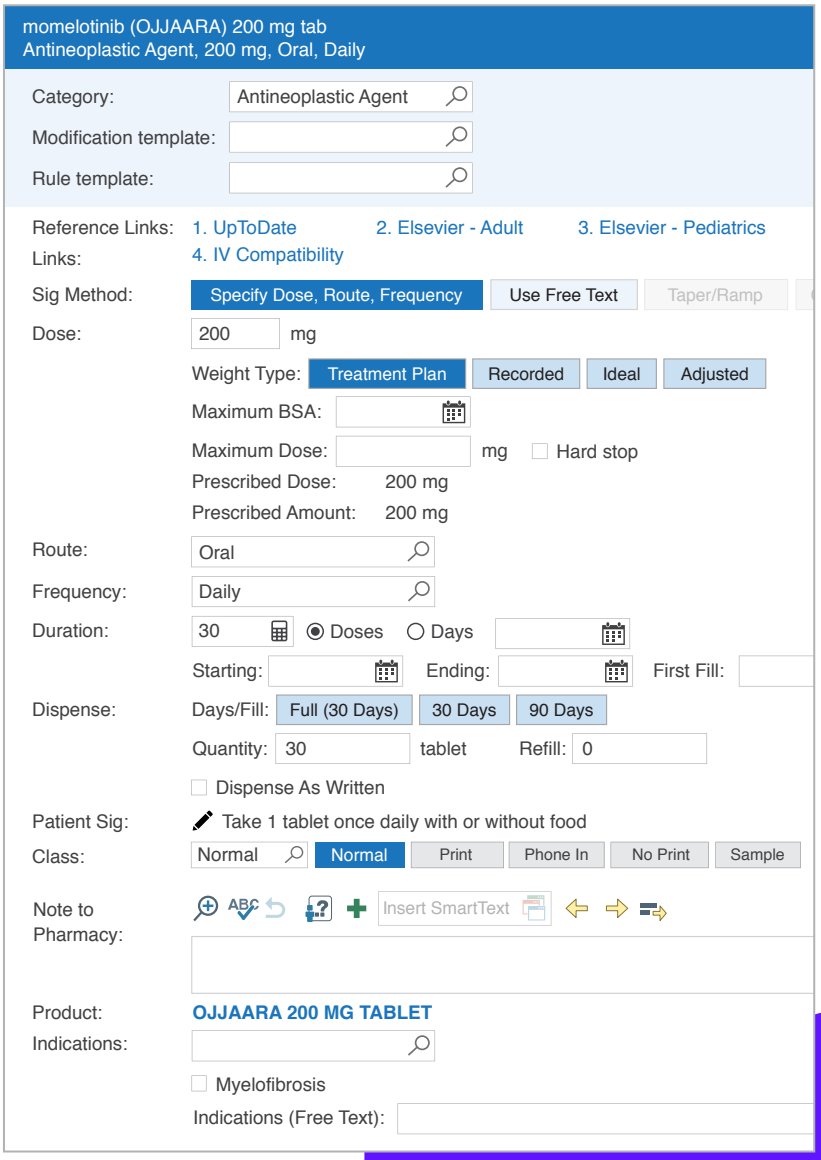
Create a New Order Group (cont'd)

6. Select **Add Order**.
7. Search for and select the appropriate **Category**.
8. Enter the **OJJAARA Initial Dose** in the **Order** field and select **Accept**.
9. Enter **Medication Details** as appropriate including dose, route, frequency, starting time and any additional order instructions, for example, an initial dose:
   - Strength: 200 mg
   - Route: Orally
   - SIG: Take 1 tablet daily for 30 days with or without food
   - Dispense: 30 tablets
   - Refills: 0
10. Select **Add Order** to create orders for other strengths of **OJJAARA** described in the Prescribing Information
    - 150 mg, Dispense 30 tablets
    - 100 mg, Dispense 30 tablets
11. Select **Accept**.
12. Repeat the process to add associated orders such as patient education and labs as recommended in the **Prescribing Information** and per clinical discretion.
13. After orders have been added, **Release** the Order Group to make the changes available and prevent other administrative users from making changes without creating a new contact.



Example of the Add Order window with a default category of Antineoplastic Agent



Example of an Order Composer in Epic

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How to Add OJJAARA Order Group to a Protocol in Epic

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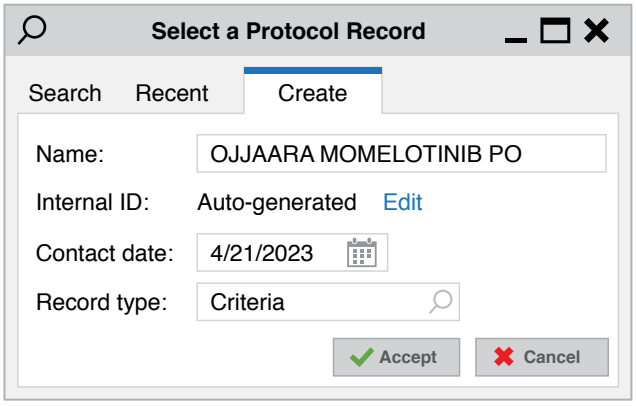
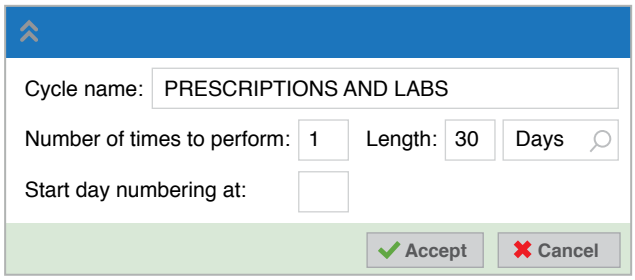
This example creates an additional protocol to which the OJJAARA Order Group can be added.

1. Navigate to **Admin** > **Beacon Admin** > **Protocol Builder** to open the Protocol Builder window.
2. Select the **Create** tab, and enter an appropriate protocol Name, according to health system conventions, for example, OJJAARA (momelotinib) PO.
3. Select **Accept**. Then, select **Accept** again to confirm.



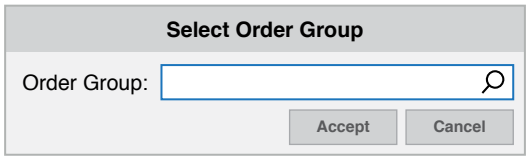
Example of the Select a Protocol Record, Create tab

4. From the menu, select **Add a Blank Cycle**.

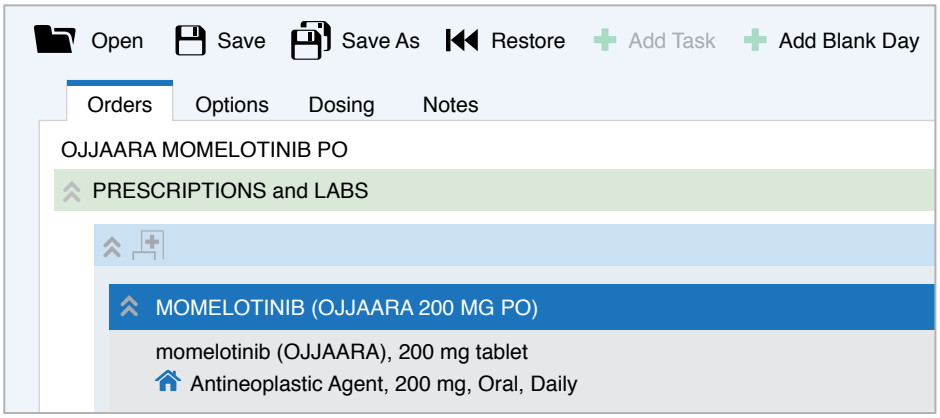


Example of creating the additional section within the Protocol

5. In **Select Order Group**, search for and select the **Order Group ID** or **Name** just created for OJJAARA.
6. Select **Accept**.



Example of Order Group selection



Example of the OJJAARA Order Group displayed within a Protocol build

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How to Add OJJAARA Order Group to a Protocol in Epic (cont'd)

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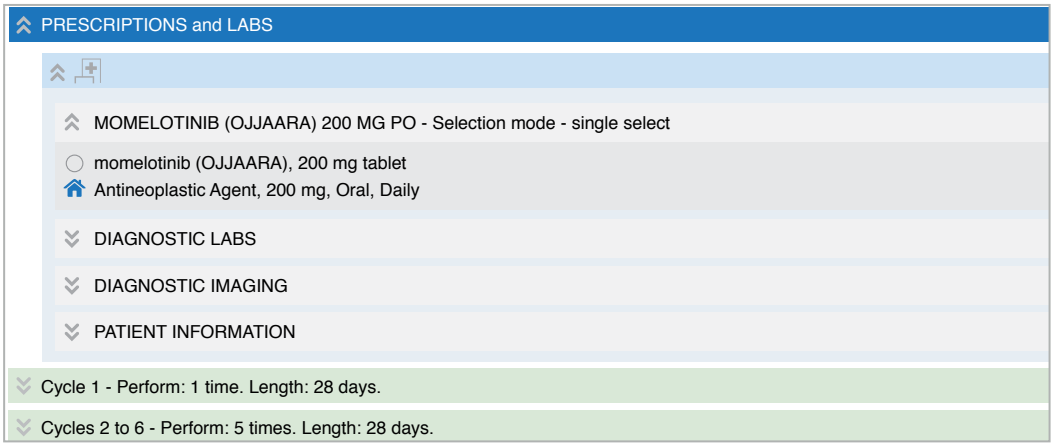
7. Add other orders as consistent with the **Prescribing Information** and per clinical discretion.
8. After orders have been added, Release the Order Group to make the changes available and prevent other administrative users from making changes without creating a new contact.



Example of the Protocol used in a patient's Treatment Plan

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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 50×10^9/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

- 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 **click here to see accompanying full Prescribing Information**.

IMPORTANT SAFETY INFORMATION (cont'd)

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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.

Please **click here to see accompanying full Prescribing Information**.

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 (≥20% in either study) are thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

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.

IMPORTANT SAFETY INFORMATION

(cont'd)

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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 **click here to see accompanying full Prescribing Information**.

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