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

ADDING OJJAARA (MOMELOTINIB) TO AN iKnowMed 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 8-10.
Click here for accompanying full Prescribing Information.

EHR=electronic health record.

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

ABOUT THIS GUIDE

This guide provides educational information to help healthcare providers who want to create Regimens that include OJJAARA or want to add OJJAARA to an existing Regimen. Regimens include 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 HCP 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 most recent version of iKnowMed. 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 the expertise and experience of 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 iKnowMed. GSK does not endorse or recommend any EHR system.

Please see the Indication and Important Safety Information on pages 8-10.
Click here for accompanying full Prescribing Information.

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

ROLE OF REGIMENS

Regimens are commonly used to help facilitate the care of patients. Regimens help enable consistency of care and streamline ordering of an entire treatment protocol including specific care instructions.

As treatment options such as OJJAARA become available, it may be necessary to create an additional Regimen or to update an existing Regimen to remove system obstacles to prescribe OJJAARA for its approved indication. Once a regimen is selected, it becomes part of the patient chart and can be managed by the Flowsheet. Updating relevant Regimens to include OJJAARA allows the care team to see that it is available for appropriate patients.

Refreshing protocols is a common process and provides an opportunity to incorporate treatment updates and guideline changes. Regimens 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 Regimen update. Various stakeholders may participate in reviewing Regimen modification requests prior to the approval.

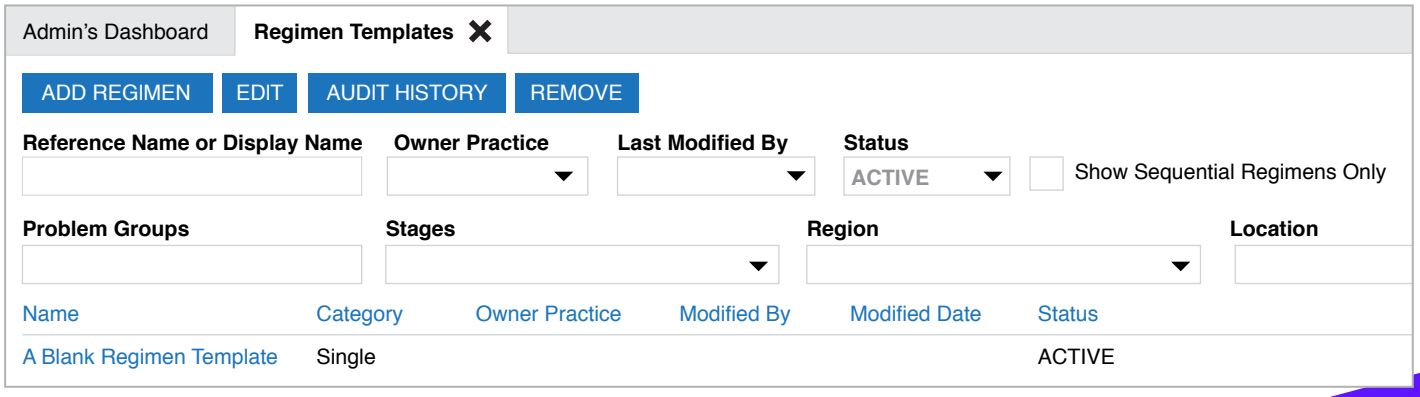
Creating or Updating a Regimen

NOTE: If OJJAARA is not available for selection in iKnowMed, 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.

Creating an Additional Regimen Template

Custom Regimen Templates can be created only with full permissions. However, a regimen template can be created using a copy of an existing regimen. A blank regimen template may be available. This guide uses a blank template as an example.

1. From the **Manage** menu, select **Regimen Templates**.
2. In the **Reference Name or Display Name** field, search for and select the Regimen to copy, for example, *A Blank Regimen Template*.



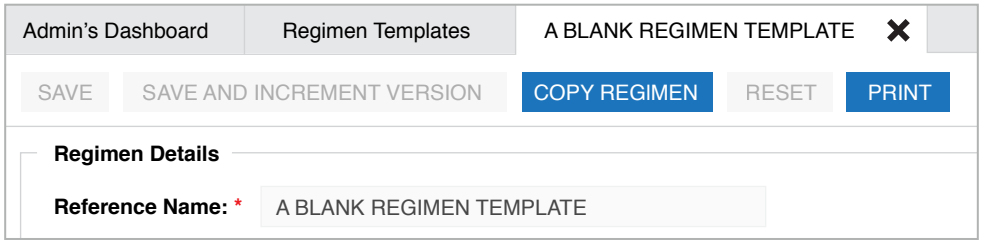
Example of a Regimen Template search

Please see the Indication and Important Safety Information on pages 8-10.
Click here for accompanying full Prescribing Information.

Creating or Updating a Regimen (cont'd)

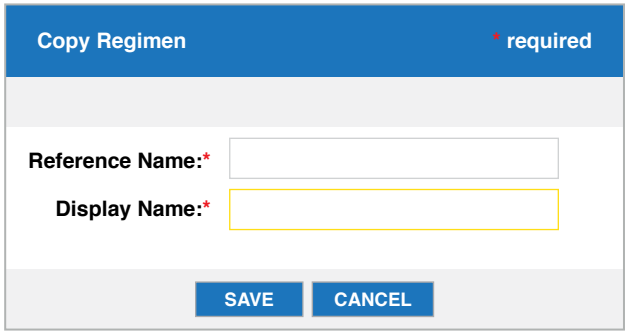
Creating an Additional Regimen Template (cont'd)

3. Select **Copy Regimen**.



Example of a Copy Regimen option

4. Enter the new **Reference Name** (internal) and the **Display Name**, for example, **OJJAARA PO**; select **Save**.



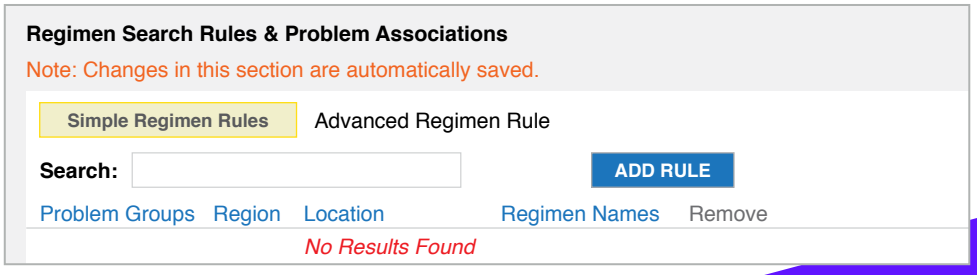
Example of naming an additional Regimen

Defining Regimen Search Rules & Problem Associations Section

The Regimen Search Rule & Problem Association enables the user to define how the Regimen will be used. This section is found at the bottom of the Regimen window.

1. Search for and select the problems for which the additional regimen is appropriate, for example, *Myelofibrosis*.
2. Define Regimen rule detail; select **Save**.
3. Select **Add Rule**.

   Note: Multiple Rules can be added to include multiple problems.



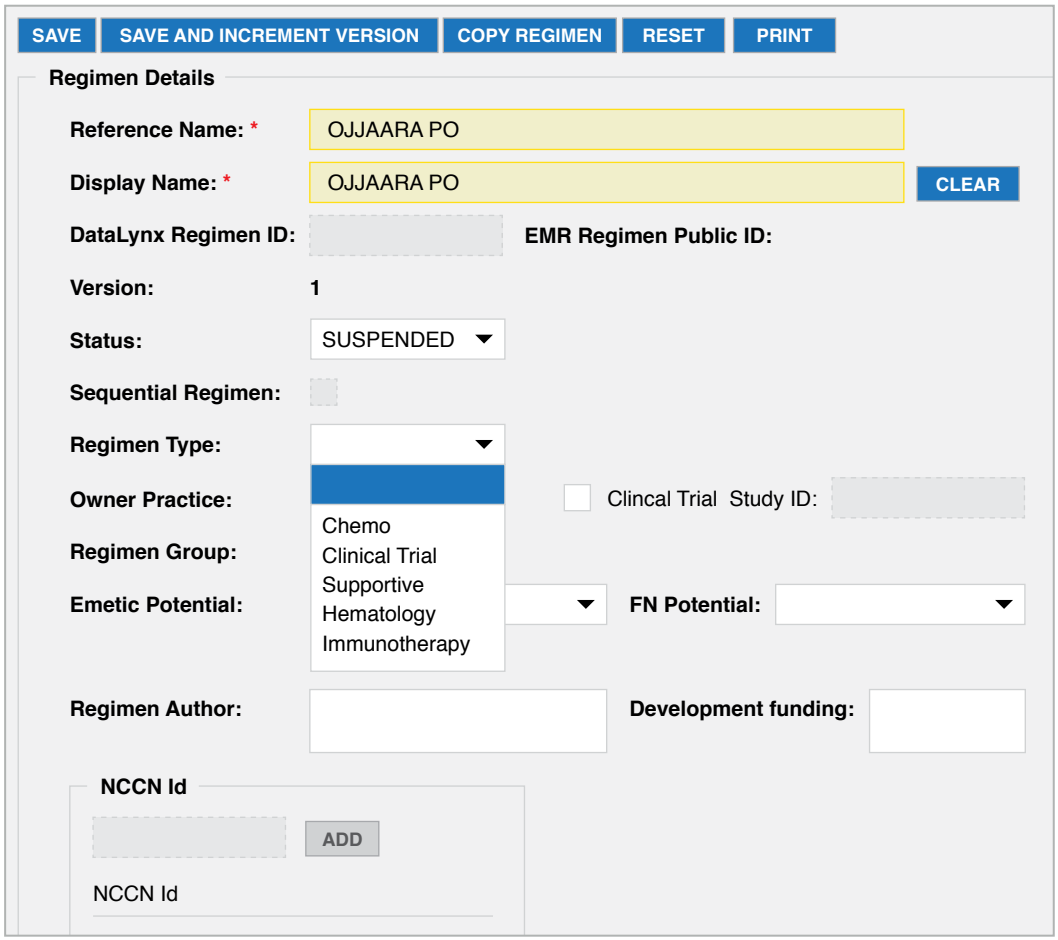
Example of assigning Problem Associations

Please see the Indication and Important Safety Information on pages 8-10.
Click here for accompanying full Prescribing Information.

Creating or Updating a Regimen (cont'd)

Defining Regimen Search Rules & Problem Associations Section (cont'd)

4. Complete the Regimen details, including the appropriate Regimen type.
5. Select **Save** to complete the Regimen information before editing the medication information.



Example of entering Regimen details

Please see the Indication and Important Safety Information on pages 8-10.
Click here for accompanying full Prescribing Information.

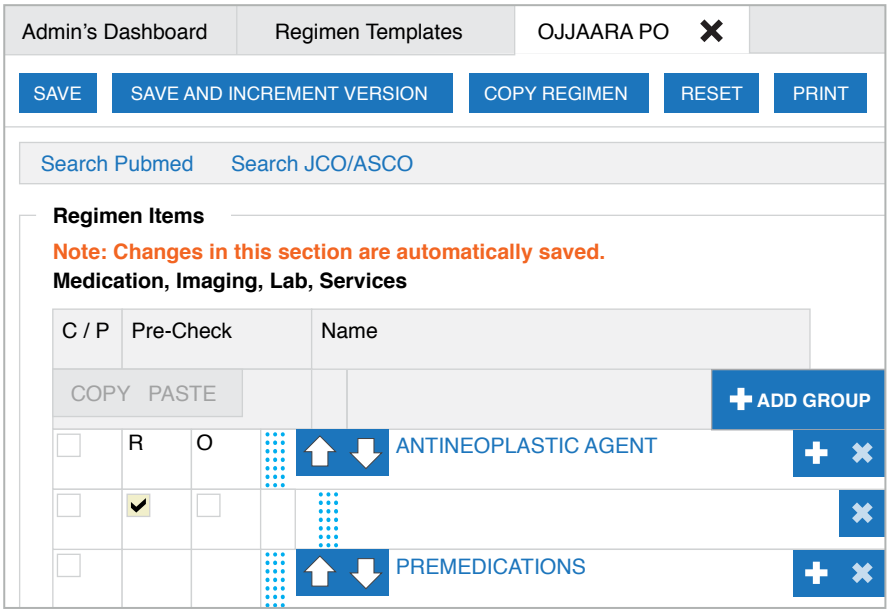
Creating or Updating a Regimen (cont'd)

Updating the Additional Regimen

1. In the Regimen Items list, add items to the Regimen. From the appropriate Treatment Group, select the **+ (plus)** on the right side of the treatment group.

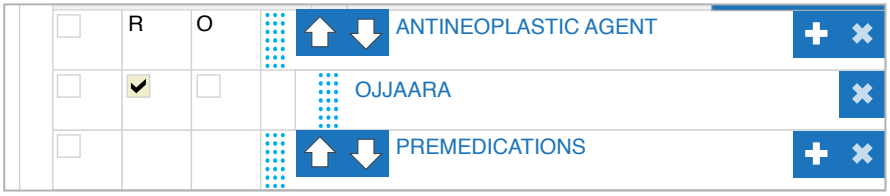
   Note: When copying from an existing non-blank Regimen, remember to remove any items from the originally copied Regimen that are inappropriate for the additional Regimen.

   Add other orders as consistent with the Prescribing Information and per clinical discretion.



Example of updating Regimen items

2. In the **Search/Add Orderables**, search for and select all doses of OJJAARA; select **Save** to add them to the template.
   - Strengths of OJJAARA include
     - OJJAARA 200 mg
     - OJJAARA 150 mg
     - OJJAARA 100 mg



Example of a medication added to the Regimen

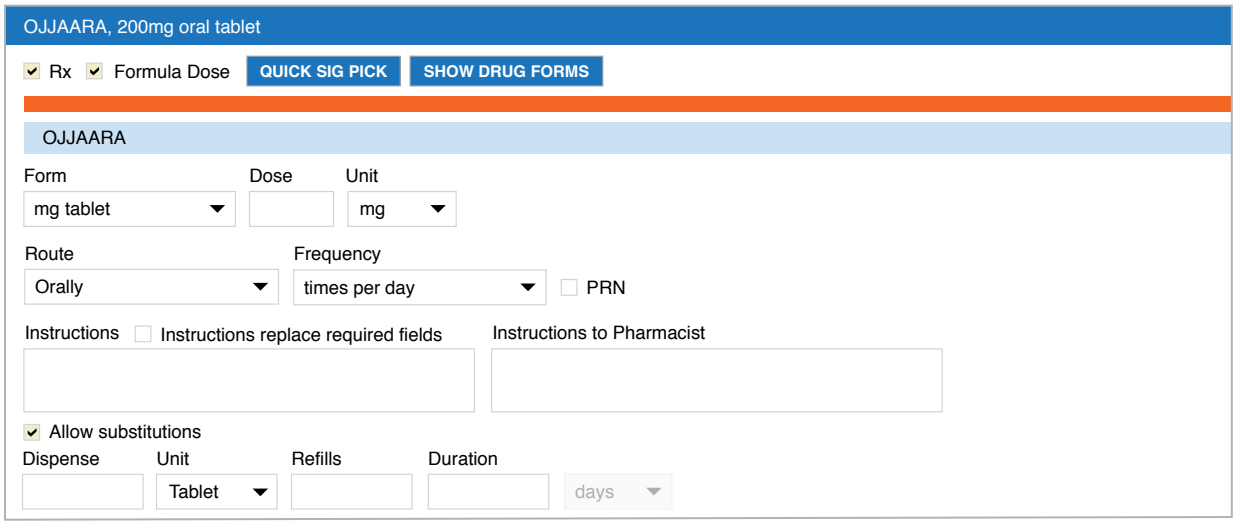
3. Select one of the OJJAARA doses from the template.

Please see the Indication and Important Safety Information on pages 8-10.
Click here for accompanying full Prescribing Information.

Creating or Updating a Regimen (cont'd)

Updating the additional Regimen (cont'd)

4. From the OJJAARA details window, select details which will default when an order is placed.
5. Check **Rx** and **Formula Dose** to enter appropriate dosing instructions. Use the **Quick SIG Pick** or **Show Drug Forms** to display preset Dose, Frequency, Form Instruction options. Select as desired.



Example of adding dosage details and instructions as defaults to the Regimen

6. Select **SAVE**.
7. Repeat steps 3-5 to set defaults for each strength, as appropriate.

Please see the Indication and Important Safety Information on pages 8-10.
Click here for accompanying full Prescribing Information.

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..

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)

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

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 (≥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.

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.

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

IMPORTANT SAFETY INFORMATION (cont'd)

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

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**.