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

Take the first step in your OJJAARA MF journey

The first and only FDA-approved treatment specifically for adults with certain types of myelofibrosis (MF) who have anemia

APPROVED USE

OJJAARA is a prescription medicine used to treat adults with certain types of myelofibrosis (MF) who have anemia. It is not known if OJJAARA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

OJJAARA may cause serious side effects, including:

- **Risk of Infections.** People who take OJJAARA may develop serious infections that can lead to death, such as bacterial and viral infections, including COVID-19. If you have an active infection, your healthcare provider should not start treatment with OJJAARA until your infection is gone. If you have had hepatitis B for a long time (chronic), OJJAARA may cause your hepatitis B to become active again, and your healthcare provider will check your blood for active hepatitis B before starting treatment.

Please see Important Safety Information throughout and on pages 14-15.
Please see accompanying full Prescribing Information, including Patient Information.

About myelofibrosis

Myelofibrosis is a rare blood cancer that affects the blood and bone marrow.

Myelofibrosis (MF) is one part of a bigger group of blood cancers called myeloproliferative neoplasms, or MPNs.

About 25,000 people in the United States have MF.

The symptoms of MF can be different for each person, which means you may not experience all of them.

Anemia

Anemia means you have a low red blood cell count. Your healthcare provider may call this low hemoglobin. When you have anemia, you may feel tired, weak, or short of breath.

- About **60%** of people are anemic within 1 year of their MF diagnosis
- **46%** need blood transfusions

Enlarged spleen

MF can cause the spleen to get too big. An enlarged spleen is called splenomegaly. If you have splenomegaly, you may feel full too quickly or have pain under your left rib.

Low platelet count

Platelets are a type of blood cell that helps your blood clot. When your body doesn't make enough platelets, it's called thrombocytopenia. Thrombocytopenia can cause problems like bleeding or bruising easily.

Other MF symptoms

MF can cause other symptoms throughout the body. Other symptoms of MF may include night sweats, pain under the left rib, weight loss, fatigue, tiredness, abdominal pain, itching, or bone pain.

Not an actual patient.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Infections (cont'd)

Your healthcare provider will monitor you and treat you for any infections that you get during treatment with OJJAARA. **Tell your healthcare provider right away if you develop any of the following symptoms of infection:**

- fever
- chills
- cough
- breathing problems
- diarrhea
- vomiting
- pain or burning feeling when passing urine

Please see Important Safety Information throughout and on pages 14-15.
Please see accompanying full Prescribing Information, including Patient Information.

Why OJJAARA?

OJJAARA is the first and only FDA-approved treatment specifically for adults with certain types of MF who have anemia. It is not known if OJJAARA is safe and effective in children.

How should I take OJJAARA?

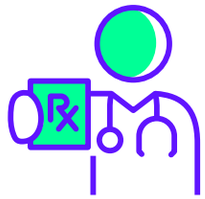
ONE PILL, ONCE DAILY

One pill, once daily

OJJAARA is a once-daily tablet you swallow whole **(don't cut, crush, or chew)**. You can take OJJAARA with or without food.

If you miss a dose of OJJAARA, skip the missed dose and take your next dose the following day at your regular time. **Do not take 2 doses at the same time to make up for the missed dose.**

Take OJJAARA exactly as your healthcare provider tells you to take it



- Your healthcare provider will do blood tests before you start taking OJJAARA and during treatment
- Do not change your dose or stop taking OJJAARA without talking to your healthcare provider first
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OJJAARA if you have certain side effects
- If you take too much OJJAARA, call your healthcare provider or go to the nearest emergency room right away and take your bottle of OJJAARA with you

For more information about OJJAARA, talk to your healthcare provider. Get tips for talking to your doctor about OJJAARA at **OJJAARA.com**

Ojjaara (momelotinib)

OJJAARA study results

Study 1: OJJAARA was studied in adults with MF symptoms* and anemia (Hb <10 g/dL) compared to danazol

Study 1 included 195 people with MF symptoms and anemia **who had taken a JAK inhibitor before**

130 people in the subset were given OJJAARA

65 people were given danazol

Treatment lasted 24 weeks

Hb=hemoglobin; JAK=Janus kinase.

*MF symptoms included night sweats, pain under ribs on left side, itching, fullness, abdominal discomfort, bone pain, and fatigue.

Primary results: The primary goal of Study 1 was to compare the percentage of people treated with OJJAARA or danazol who were able to reduce their overall MF symptom score† by 50% or more from the beginning of the study to Week 24.

REDUCED MF SYMPTOM SCORE†

MF symptom score was reduced by 50% or more in:

- **25%** (32 out of 130) of people taking OJJAARA
- **9%** (6 out of 65) of people taking danazol

Secondary results: A secondary goal of the study was to compare the percentage of people treated with OJJAARA or danazol who were able to reduce their spleen size by 35% or more from the beginning of the study to Week 24. Another secondary goal was to see if the percentage of people who were transfusion independent‡ between Weeks 12 and 24 was similar for people taking OJJAARA versus danazol.

REDUCED SPLEEN SIZE

Spleen size was reduced by 35% or more in:

- **22%** (29 out of 130) of people taking OJJAARA
- **3%** (2 out of 65) of people taking danazol

TRANSFUSION INDEPENDENCE‡

A similar percentage of people were transfusion independent between Weeks 12 and 24. This was seen in:

- **30%** (39 out of 130) of people taking OJJAARA
- **20%** (13 out of 65) of people taking danazol

†The symptom score was measured using a form that tracked MF symptoms like fatigue, night sweats, bone pain, and others during treatment.

‡No transfusion or Hb <8 g/dL.

Not an actual patient.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Low platelet and white blood cell counts.** OJJAARA may cause new or worsening low platelet and white blood cell counts. Low platelet counts may increase your risk for bleeding and low white blood cell counts may increase your risk for infection. Your healthcare provider will do blood tests to check your blood counts before you start taking OJJAARA and during treatment. Tell your healthcare provider right away if you have any signs of bleeding during treatment with OJJAARA, including:
  - unusual bleeding
  - bruising
  - black or tarry stools

Please see Important Safety Information throughout and on pages 14-15. Please see accompanying full Prescribing Information, including Patient Information.

Ojjaara (momelotinib)

Not an actual patient.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Liver problems.** OJJAARA may cause new or worsening increased liver enzymes and bilirubin in your blood. Your healthcare provider will check your liver enzymes before starting treatment, every month for the first 6 months of treatment, and then as needed during treatment with OJJAARA. Your healthcare provider may stop treatment with OJJAARA if your liver enzymes increase. Tell your healthcare provider if you develop any of the following signs or symptoms of liver problems:
  - tiredness
  - loss of appetite
  - pain in your right upper stomach area (abdomen)
  - dark urine
  - yellowing of your skin or the white part of your eyes

OJJAARA study results (cont'd)

Study 2: OJJAARA was compared to ruxolitinib in a study of 432 adults with MF who had never taken a JAK inhibitor before

From this study, a **subset**, or **smaller group**, of 181 patients who had anemia (Hb <10 g/dL) at the start of the study were evaluated

86 people in the subset were given OJJAARA

95 people were given ruxolitinib

Treatment lasted 24 weeks

- **In Study 2, how well OJJAARA worked in patients who had MF with anemia was based on spleen size reduction**
- **A lower percentage of patients had their total symptom score reduced by 50% or more when treated with OJJAARA (25%) compared with ruxolitinib (36%) at Week 24**

Spleen size results: A goal of this study was to see if OJJAARA was similar to ruxolitinib in reducing spleen size in people with MF who have anemia. This means that a similar percentage of people in both groups would see a reduction in spleen size of 35% or more at Week 24 compared to the start of the study.

SIMILAR SPLEEN SIZE REDUCTION

Spleen size was reduced by 35% or more in:
- **31%** (27 out of 86) of people with anemia taking OJJAARA
- **33%** (31 out of 95) of people with anemia taking ruxolitinib

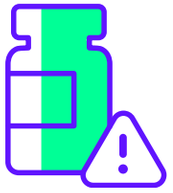
Please see Important Safety Information throughout and on pages 14-15. Please see accompanying full Prescribing Information, including Patient Information.

Ojjaara (momelotinib)

What can I expect while taking OJJAARA?

- **Your doctor will do blood tests before you start taking OJJAARA and during treatment**
- **Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OJJAARA if you have certain side effects**

What are the possible serious side effects of OJJAARA?



Possible serious side effects of OJJAARA include:

- Risk of infections
- Low platelet and white blood cell counts
- Liver problems
- Major cardiovascular events such as heart attack, stroke, and death
- Blood clots
- New cancers

See more information on these possible serious side effects on pages 14-15.

What are the possible side effects of OJJAARA?

The most common side effects of OJJAARA include:

- Low platelet count
- Bleeding
- Bacterial infection
- Tiredness
- Dizziness
- Diarrhea
- Nausea

These are not all of the possible side effects of OJJAARA.

Call your doctor for medical advice about side effects.
Report negative side effects of prescription drugs to the FDA.
Visit **www.fda.gov/medwatch**, or call **1-800-FDA-1088**.

Please see Important Safety Information throughout and on pages 14-15.
Please see accompanying full Prescribing Information, including Patient Information.

Together with GSK Oncology

Together with GSK Oncology is a patient support program to help you and your doctor access a variety of reimbursement support and financial assistance offerings that you may be eligible for if you are prescribed OJJAARA.

Together with GSK Oncology offers a dedicated team of reimbursement support counselors who:

- **Look into your insurance** and work with your doctor to **provide information about your plan's coverage and benefits***
- **Offer co-pay assistance** for eligible, commercially insured patients who may receive their OJJAARA for as little as $0 up to an annual program maximum of $26,000
- Provide information about other organizations or independent foundations that may be able to help with OJJAARA costs
- Can help determine if you are eligible for the **Patient Assistance Program, offering OJJAARA for free if eligible,** for those with no prescription drug coverage, or Medicare patients who qualify for the program

Refer to togetherwithgskoncology.com for information about eligibility and full program terms and conditions.

Learn more about **Together with GSK Oncology** and how the program may help in your treatment journey.

1-844-4GSK-ONC (1-844-447-5662)
TogetherwithGSKOncology.com

*The information provided by Together with GSK Oncology is not a guarantee of coverage or reimbursement.

Ojjaara (momelotinib)

Not an actual patient

Notes

APPROVED USE

OJJAARA is a prescription medicine used to treat adults with certain types of myelofibrosis (MF) who have anemia. It is not known if OJJAARA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

OJJAARA may cause serious side effects, including:

- **Risk of Infections.** People who take OJJAARA may develop serious infections that can lead to death, such as bacterial and viral infections, including COVID-19. If you have an active infection, your healthcare provider should not start treatment with OJJAARA until your infection is gone. If you have had hepatitis B for a long time (chronic), OJJAARA may cause your hepatitis B to become active again, and your healthcare provider will check your blood for active hepatitis B before starting treatment. Your healthcare provider will monitor you and treat you for any infections that you get during treatment with OJJAARA. **Tell your healthcare provider right away if you develop any of the following symptoms of infection:**
  - fever
  - chills
  - cough
  - breathing problems
  - diarrhea
  - vomiting
  - pain or burning feeling when passing urine
- **Low platelet and white blood cell counts.** OJJAARA may cause new or worsening low platelet and white blood cell counts. Low platelet counts may increase your risk for bleeding and low white blood cell counts may increase your risk for infection. Your healthcare provider will do blood tests to check your blood counts before you start taking OJJAARA and during treatment. Tell your healthcare provider right away if you have any signs of bleeding during treatment with OJJAARA, including:
  - unusual bleeding
  - bruising
  - black or tarry stools
- **Liver problems.** OJJAARA may cause new or worsening increased liver enzymes and bilirubin in your blood. Your healthcare provider will check your liver enzymes before starting treatment, every month for the first 6 months of treatment, and then as needed during treatment with OJJAARA. Your healthcare provider may stop treatment with OJJAARA if your liver enzymes increase. Tell your healthcare provider if you develop any of the following signs or symptoms of liver problems:
  - tiredness
  - loss of appetite
  - pain in your right upper stomach area (abdomen)
  - dark urine
  - yellowing of your skin or the white part of your eyes
- **Major cardiovascular events such as heart attack, stroke, and death.** Major cardiac events have happened, especially in people with cardiac risk factors and who are current or past smokers, taking another Janus kinase (JAK) inhibitor to treat rheumatoid arthritis. OJJAARA is in the JAK family of medicines. **Get emergency help right away if you have any symptoms of a heart attack or stroke while taking OJJAARA, including:**
  - discomfort in your chest that lasts for more than a few minutes, or that goes away and comes back
  - severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
  - pain or discomfort in your arms, back, neck, jaw, or stomach
  - shortness of breath with or without chest discomfort
  - breaking out in a cold sweat
  - nausea or vomiting
  - feeling lightheaded
  - weakness in one part or on one side of your body
  - slurred speech
- **Blood clots.** Blood clots in the veins of the legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) have happened in some people taking another JAK inhibitor to treat rheumatoid arthritis, and may be life-threatening. Tell your healthcare provider if you have had blood clots in the veins of your legs or lungs in the past. **Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with OJJAARA**, including:
  - swelling, pain, or tenderness in one or both legs
  - sudden, unexplained chest pain
  - shortness of breath or difficulty breathing
- **New cancers.** New cancers, including lymphoma and other cancers, except non-melanoma skin cancer, have happened in some people taking another JAK inhibitor to treat rheumatoid arthritis. The risk of new cancers is further increased in people who smoke or who smoked in the past.

The most common side effects of OJJAARA include:

- low platelet count
- bleeding
- bacterial infection
- tiredness
- dizziness
- diarrhea
- nausea

These are not all the possible side effects of OJJAARA. Call your doctor for medical advice about side effects.

Before taking OJJAARA, tell your healthcare provider about all your medical conditions, including if you:

- have an infection
- have or have had hepatitis B
- have or have had liver problems
- have had a heart attack, or have or have had other heart problems, or stroke
- have or have had a blood clot
- smoke or were a smoker in the past
- have or have had any other cancers
- are pregnant or plan to become pregnant. OJJAARA may harm your unborn baby. **Females who are able to become pregnant:**
  - You should use effective birth control (contraception) during treatment and for 1 week after the last dose of OJJAARA.
  - Tell your healthcare provider right away if you think you are pregnant or become pregnant during treatment with OJJAARA.
- are breastfeeding or plan to breastfeed. It is not known if OJJAARA passes into your breast milk. You should not breastfeed during treatment and for 1 week after the last dose of OJJAARA. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking OJJAARA with certain other medicines may affect the amount of OJJAARA or the other medicines in your blood and may increase your risk of side effects.

You are encouraged to report negative side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information, including Patient Information for patients.

Ojjaara (momelotinib)

Scan here and get to know OJJAARA.
Visit OJJAARA.com

Please see Important Safety Information throughout and on pages 14-15. Please see accompanying full Prescribing Information, including Patient Information.

MMLBROC240002 February 2024
Produced in USA.

Ojjaara (momelotinib) | GSK