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

Take the next step in your myelofibrosis (MF) journey with OJJAARA

The first and only FDA-approved treatment specifically for adults with certain types of myelofibrosis 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 10-11.
Please see full Prescribing Information, including Patient Information.

What is myelofibrosis?

Myelofibrosis (my-ah-lo-fye-BRO-sis; MF) is one part of a bigger group of blood cancers called myeloproliferative neoplasms, or MPNs, that affect the blood and bone marrow.

About 25,000 people in the United States have myelofibrosis.
The symptoms of myelofibrosis 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.

Within 1 year of their myelofibrosis diagnosis:

- About **60%** of people are **anemic**
- **46%** need **blood transfusions**

Enlarged spleen

Myelofibrosis 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 help your blood clot. When your body doesn't make enough platelets, it's called thrombocytopenia. This can cause problems like bleeding or bruising easily.

Other myelofibrosis symptoms

Myelofibrosis can also cause other symptoms that can impact your body in different ways. This can include night sweats, pain under the left rib, weight loss, fatigue, tiredness, abdominal pain, itching, or bone pain.

OJJAARA: One pill, once daily

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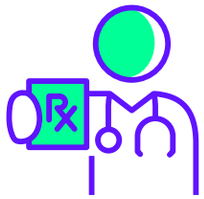
How should I take OJJAARA?

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**

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

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Clinical trial design and results for OJJAARA

Two different groups of people with MF with anemia (Hb <10 g/dL) took part in two 24-week clinical trials testing OJJAARA (oh-JAR-ruh) against two other treatments:

STUDY 1: 195 people with MF symptoms and anemia who had taken a JAK inhibitor before

130 people were given OJJAARA

65 people were given danazol

The primary goal of STUDY 1 was to compare the percentage of people treated with OJJAARA or danazol who reduced their overall MF symptom score* by 50% or more from the start of the study to Week 24. Secondary goals were comparing the percentage of people who reduced their spleen size by 35% or more and to see if the percentage of people who were transfusion independent† was similar in both treatment groups between Weeks 12 and 24.

REDUCED MF SYMPTOM SCORE* BY 50% OR MORE IN:

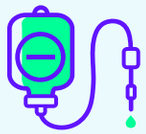
- **25%** of people taking OJJAARA
- **9%** of people taking danazol

REDUCED SPLEEN SIZE BY 35% OR MORE IN:

- **22%** of people taking OJJAARA
- **3%** of people taking danazol

TRANSFUSION INDEPENDENCE† BETWEEN WEEKS 12 AND 24 IN:

- **30%** of people taking OJJAARA
- **20%** of people taking danazol



After 24 weeks of treatment, this study showed that, of the people taking OJJAARA: 1 in 4 had a reduced symptom score, over 1 in 5 had a reduced spleen size, and close to 1 in 3 experienced transfusion independence. Individual patient results may vary.

Hb=hemoglobin; JAK=Janus kinase; RBC=red blood cell.

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

†Transfusion independence meant no RBC transfusions were needed and all Hb levels were ≥8 g/dL during the time period between Weeks 12 and 24.

STUDY 2: 432 people with MF with an enlarged spleen who had never taken a JAK inhibitor before

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

86 people were given OJJAARA

95 people were given ruxolitinib

A goal of this study was to see if OJJAARA was similar to ruxolitinib in reducing spleen size in people who have MF with 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.

In STUDY 2, how well OJJAARA worked in patients who had MF with anemia was based on spleen size reduction. After 24 weeks of treatment, this study showed that, of the people taking OJJAARA, almost 1 in 3 had a reduced spleen size and 1 in 4 had a reduced symptom score. Individual patient results may vary.

SIMILAR SPLEEN SIZE REDUCTION OF 35% OR MORE IN:

- **31%** of people with anemia taking OJJAARA
- **33%** of people with anemia taking ruxolitinib

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.

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
  - black or tarry stools
  - bruising

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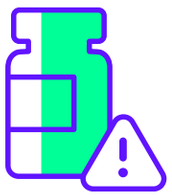
Ojjaara (momelotinib)

What can I expect while taking OJJAARA?

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

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 10-11.

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.**

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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 copay 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

Visit 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.

†The maximum amount available per year from the copay program is $26,000. Patients in health plans that do not allow the amounts available from the copay program to count towards their copay, coinsurance, deductible, or other out-of-pocket cost sharing obligations, sometimes referred to as "maximizer plans," are subject to a yearly program maximum of $16,000.

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  - 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.

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

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