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

Starting OJJAARA

- **Myelofibrosis with anemia can affect each person differently.** As you start your treatment with OJJAARA, it's important to understand that the time it may take to experience results may not be the same for everyone
- **Your doctor will do blood tests before you start taking OJJAARA and during treatment.** This will help them keep track of your health, any side effects you may experience, and how OJJAARA is working for you
- **In clinical trials, it took about 6 months or longer for some people to see results.** Some people may see results earlier, and some may not respond to treatment at all. Your care team will support and guide you throughout your treatment. Reach out to them with any questions

What could this mean for you?

If you don't notice any improvement in your symptoms right away, keep in mind:

- OJJAARA may take time to work, but it might help make a difference in your symptoms over time
- You should continue going to your follow-up appointments and taking your medication as prescribed
- Your doctor will monitor your symptoms and progress and make dose adjustments if needed

OJJAARA is one pill taken once daily.

OJJAARA is available in 3 dosage strengths:

100 mg	150 mg	200 mg
		
(9 mm)	(11 mm)	(15 mm)

Pill sizes are smaller than a dime.

(17.91 mm)

Take OJJAARA exactly as your doctor tells you to take it. Your doctor may change your dose, temporarily stop, or permanently stop treatment with OJJAARA if you have certain side effects.

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 additional Important Safety Information throughout. Please see full Prescribing Information, including Patient Information.

Clinical trial design for OJJAARA

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

- **In the first trial**, people taking OJJAARA were compared with people taking danazol
  - — **The primary goal** of the trial was to see how many people reduced their overall myelofibrosis symptom score by 50% or more over the course of 24 weeks
  - — **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
- **In the second trial**, people taking OJJAARA were compared with people taking ruxolitinib
  - — A goal of this study was to see if OJJAARA was similar to ruxolitinib in reducing spleen size in people who have myelofibrosis with anemia
  - — A similar percentage of people in both groups saw a reduction in spleen size of 35% or more at Week 24 compared to the start of the study, with 1 in 3 people taking OJJAARA having a reduced spleen size and 1 in 4 having a reduced symptom score

General guidance for managing side effects

- You will be monitored frequently for the first several months after starting OJJAARA
- Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements
- Ask your doctor about over-the-counter medications that may help with certain side effects

Notes:

Hb=hemoglobin.

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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Ojjaara (momelotinib)

The most common side effects of OJJAARA include:	Tips to help manage them:
Low platelet count	• Be careful not to burn yourself • Talk to your doctor about whether or not it is okay to drink alcohol • When cleaning your nose, blow gently into a soft tissue
Bleeding	• Use an extra soft toothbrush and follow your dentist's and doctor's advice for caring for your teeth and gums • Try to avoid getting cuts or nicks to your skin • Use an electric shaver instead of a razor
Bacterial infection	• Don't squeeze, pick, or scratch at wounds or blemishes • Avoid cutting or tearing your fingernail and toenail cuticles • Wear protective gloves when gardening or cleaning up after animals, young children, or others • Frequently wash your hands, especially before eating and before and after using the bathroom
Tiredness	• Eat a balanced diet that provides sufficient fluid, calories, protein, vitamins, and minerals —Drink plenty of noncaffeinated liquids throughout the day —Add iron-rich foods such as green leafy vegetables and red meat —Eat frequent small meals or snacks throughout the day
Dizziness	• If lying down, try sitting up slowly, as sudden movements could increase the risk of losing your balance • A low-salt diet may help to reduce dizziness
Diarrhea	• Drink clear liquids to stay hydrated • If experiencing diarrhea, eat foods that are easier to digest, such as white rice, puffed cereal, soft fruits, and cooked vegetables without skins • Avoid foods that can make diarrhea worse, such as spicy foods, high-fiber foods, high-fat foods, and raw fruits and vegetables
Nausea	• If experiencing nausea, try eating dry, bland foods, such as crackers or toast. Avoid foods that may trigger nausea such as fried foods, spicy foods, or foods with strong smells • Drink plenty of water and fluids, especially after vomiting, to stay hydrated • Stay sitting up after eating

These are not all the possible side effects of OJJAARA, but they are the most common. Make sure that you are communicating with your doctor about any side effects you experience and to get medical advice on how to address side effects.

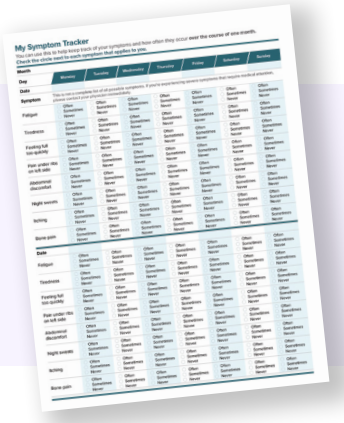
Please see additional Important Safety Information throughout. Please see full Prescribing Information, including Patient Information.

Ojjaara (momelotinib)

Potential serious side effects

- **Risk of infections**
  - — Tell your healthcare provider right away if you develop any symptoms of infection, such as fever, chills, cough, breathing problems, diarrhea, vomiting, or a pain or burning feeling when passing urine
- **Low platelet and white blood cell counts**
  - — Tell your healthcare provider right away if you show any signs of unusual bleeding, bruising, or black or tarry stools
- **Liver problems**
  - — Tell your healthcare provider right away if you develop tiredness, loss of appetite, pain in your abdomen, dark urine, or yellowing of your skin or the white part of your eyes
- **Severe skin reactions**
  - — Tell your healthcare provider or get medical help right away if you get any of the following signs or symptoms of severe skin reactions, with or without fever: rash that keeps getting worse, skin pain or burning, severe rash, blistering of the lips, eyes, or mouth, reddened skin, blisters on the skin, flu-like symptoms, or skin peeling
- **Major cardiovascular events such as heart attack or stroke**
  - **— Get emergency help right away if you have any symptoms of a heart attack or stroke while taking OJJAARA, which can include discomfort; pain or tightness in your chest, throat, neck, or jaw; cold sweats; nausea or vomiting; lightheadedness; or slurred speech**
- **Blood clots**
  - — Tell your healthcare provider right away if you develop swelling, pain, or tenderness in one or both legs; sudden, unexplained chest pain; or shortness of breath or difficulty breathing
- **New cancers such as lymphoma**
  - — Tell your healthcare provider if you smoke, as the risk of new cancers is further increased in people who smoke or who smoked in the past

Please see full Prescribing Information, including Patient Information, for a more detailed view of serious side effects.



To keep a record of any potential side effects you experience, visit ojjaara.com/savings-and-support/resources/ to download the Symptom Tracker

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

Please see additional Important Safety Information throughout.

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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
- **Severe skin reactions.** Severe skin reactions that can be life-threatening have occurred with OJJAARA. **Tell your healthcare provider or get medical help right away if you get any of the following signs or symptoms of severe skin reactions, with or without fever:**
  - rash that keeps getting worse
  - severe rash
  - reddened skin
  - flu-like symptoms
  - skin pain or burning
  - blistering of the lips, eyes, or mouth
  - blisters on the skin
  - skin peeling
- **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 of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report negative side effects to GSK at gsk.public.reportum.com or 1-888-825-5249.

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Support and reimbursement

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.

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.

Notes:

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Produced in USA.

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