

## **Getting started with OJJAARA**

Welcome to your guide for getting started with OJJAARA (momelotinib). OJJAARA is the first and only FDA-approved treatment specifically for adults with certain types of myelofibrosis (MF) who have anemia. It is not known if OJJAARA is safe and effective in children. Your doctor prescribed OJJAARA to help treat your MF. The information in this guide can help you better understand what to expect when starting OJJAARA.

#### Before you start OJJAARA

Make sure you tell your healthcare provider about any medical conditions you have before you start taking OJJAARA. Some health issues to mention to your healthcare team are if you:

have an infection

- · have or have had a blood clot
- have or have had hepatitis B
- smoke or were a smoker in the past
- have or have had liver problems
- have or have had any other cancers
- have had a heart attack, or have
  - or have had other heart problems, or stroke

If you are pregnant, plan to become pregnant, could become pregnant, or are breastfeeding, see additional information on inside pages.

#### **Know your medicines**

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. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Keep a list of the medicines you take and bring the list with you to show your healthcare provider or pharmacist whenever you get a new medicine. The chart below can help you get started.

Medicine name	Why do I take this medicine?	Date started

## **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:

<ul><li>fever</li></ul>	– cough	<ul><li>diarrhea</li></ul>	<ul> <li>pain or burning feeling</li> </ul>
- chills	<ul> <li>breathing problems</li> </ul>	<ul><li>vomiting</li></ul>	when passing urine

Please see <u>Important Safety Information</u> throughout and on back cover. Please see accompanying full Prescribing Information, including Patient Information.

#### How to take OJJAARA

Get answers to frequently asked questions about taking OJJAARA.

#### How do I take OJJAARA?



## Take OJJAARA exactly as your healthcare provider tells you to take it. OJJAARA is a once-daily tablet

you swallow whole (don't cut, crush, or chew). Don't stop or change your dose of OJJAARA without first talking to your healthcare provider.

#### Do I have to take OJJAARA with food?

You can take OJJAARA with or without food.

### What should I do if I forget to take OJJAARA?

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.**Do not change your dose or stop taking OJJAARA without first talking to your healthcare provider.

## Will my healthcare provider monitor me while I'm taking OJJAARA?

Your healthcare provider will do blood tests before you start taking OJJAARA and during treatment. This will help them keep track of your health and how OJJAARA is working for you. If you have certain side effects, your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OJJAARA.

**OJJAARA** is a once-daily pill for adults with certain types of MF who have anemia



## **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 bleedingbruising
  - black or tarry stools

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



#### What should I do if I take too much OJJAARA?

Call your healthcare provider or go to the nearest emergency room right away if you take too much OJJAARA. Be sure to take your bottle of OJJAARA with you.

#### How should I store OJJAARA?

Store OJJAARA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep OJJAARA in its original bottle. The OJJAARA bottle contains a desiccant packet to help keep your tablets dry (protect from moisture). Keep the desiccant in the bottle. Tightly close the OJJAARA bottle after you take your dose.

Keep OJJAARA and all medicines out of the reach of children.

## Can OJJAARA be taken during pregnancy?

If you are pregnant, plan to become pregnant, or become pregnant while taking OJJAARA, tell your healthcare team right away. OJJAARA may harm your unborn baby. Females who are able to become pregnant 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.

## Is it safe to breastfeed when taking OJJAARA?

Talk to your healthcare team if you 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.

For more information about OJJAARA, talk to your healthcare provider. Visit OJJAARA.com





## 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
- 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 lifethreatening. 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 dizziness
- bleedingdiarrhea
- bacterial infectionnausea
- tiredness

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 accompanying full <u>Prescribing Information</u>, including <u>Patient Information</u> for patients.

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