

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using OMJJARA?

OMJJARA contains the active ingredient momelotinib, a type of medicine known as a protein kinase inhibitor. OMJJARA is used to treat adults with some forms of myelofibrosis, a rare form of blood cancer affecting the bone marrow, who also have anaemia (a reduced number of red blood cells), reduce the size of their spleen, and relieve other symptoms related to the disease.

For more information, see Section [1. Why am I using OMJJARA?](#) in the full CMI.

### 2. What should I know before I use OMJJARA?

Do not use if you have ever had an allergic reaction to momelotinib or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, had heart trouble or a stroke, have or have had hepatitis B, are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use OMJJARA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with OMJJARA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use OMJJARA?

- The recommended dosage of OMJJARA for adults is 200 mg taken orally once daily, taken with or without food.

More instructions can be found in Section [4. How do I use OMJJARA?](#) in the full CMI.

### 5. What should I know while using OMJJARA?

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Things you should do        | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using OMJJARA.</li><li>• Tell your doctor if you are pregnant, think you are pregnant or are planning to have a baby.</li><li>• Tell your doctor if you are breastfeeding or intend to breastfeed.</li><li>• Tell your doctor if you have unusual bleeding or bruising under the skin, signs of an infection or have, or ever had liver problems.</li></ul> |
| Things you should not do    | <ul style="list-style-type: none"><li>• Do not stop taking OMJJARA unless your doctor tells you to.</li></ul>                                                                                                                                                                                                                                                                                                                                                       |
| Driving or using machines   | <ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how OMJJARA affects you.</li><li>• OMJJARA may cause dizziness or blurred vision in some people.</li></ul>                                                                                                                                                                                                                                          |
| Looking after your medicine | <ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place away from moisture, heat or sunlight.</li><li>• Keep your tablets in the bottle with the desiccant until it is time to take them.</li></ul>                                                                                                                                                                                                                                           |

For more information, see Section [5. What should I know while using OMJJARA?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include diarrhoea, low platelets (components in the blood that help with clotting), nausea, headache, dizziness, fatigue, feeling weak, abdominal pain, rash and cough.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# OMJJARA

Active ingredient(s): *momelotinib*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using OMJJARA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OMJJARA.**

**Where to find information in this leaflet:**

1. [Why am I using OMJJARA?](#)
2. [What should I know before I use OMJJARA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use OMJJARA?](#)
5. [What should I know while using OMJJARA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I taking OMJJARA?

**OMJJARA contains the active ingredient momelotinib**, which is a type of medicine known as a protein kinase inhibitor.

OMJJARA blocks the action of certain proteins, called Janus Kinases (JAK1, JAK2) and ACVR1. By doing so, it can relieve the symptoms of *myelofibrosis*. With *myelofibrosis*, the bone marrow is replaced by scar tissue, and small proteins called *cytokines* are released in large numbers. The abnormal marrow can no longer produce enough normal blood cells, the spleen can become enlarged, and patients get symptoms such as fever, night sweats, bone pain, and itching.

**OMJJARA is used to treat adults with myelofibrosis, a rare form of blood cancer affecting the bone marrow, who also have anaemia (a reduced number of red blood cells), reduce the size of their spleen, and relieve other symptoms related to the disease.**

Myelofibrosis may be:

- *primary myelofibrosis*, which develops in people who have not had problems with their bone marrow before;
- *secondary myelofibrosis*, which develops in people who have other blood cancers, causing their body to produce too many red blood cells or blood cells called platelets (*post polycythaemia vera myelofibrosis* or *post essential thrombocythaemia myelofibrosis*).

## 2. What should I know before I take OMJJARA?

### Things you should do

Before taking OMJJARA, tell your healthcare provider about all of your medical conditions, including if you have had heart trouble or a stroke, have or have had hepatitis B.

### Warnings

#### Do not use OMJJARA if:

- you are allergic to momelotinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

#### Check with your doctor if you:

- have unusual bleeding or bruising under the skin, longer than usual bleeding after your blood has been drawn, or bleeding from your gums - these may be signs of a low blood platelet count.
- have an infection - signs of an infection may include fever, chills, cough, breathing problems, diarrhoea, vomiting, pain or burning feeling when passing urine.
- if you have, or ever had, any liver problems. Your doctor may need to prescribe a different dose of OMJJARA.
- If you had hepatitis B for a long time (chronic) as hepatitis B may become active again.
- have any other medical conditions.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Blood tests

Before and during treatment, you will have blood tests to check your blood cell levels (red blood cells, white blood cells and platelets) and your liver function. Your doctor may adjust the dose or stop treatment based on the results of the blood tests.

### Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to have a baby, **tell your doctor** before you take this medicine as it could harm your baby.

If you are a woman who could become pregnant you must use highly effective **contraception** while you are taking OMJJARA, and you must continue to use highly effective

contraception for at least 1 week after taking your last dose. Your doctor may ask you to take a pregnancy test, to confirm that you are not pregnant, before starting your treatment.

**Contact your doctor immediately if you become pregnant while you are taking OMJJARA.**

**Do not breast-feed while taking OMJJARA.** It is not known if it passes into breast milk.

You must stop breast-feeding before taking OMJJARA. **Do not begin breast-feeding again until at least 1 week** after taking your last dose.

**Tell your doctor if you are breast-feeding before taking this medicine.**

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with OMJJARA and affect how it works.**

**It is important that you mention any medicines containing any of the following active substances, as your doctor may need to adjust the dose of OMJJARA or the other medicine:**

- rosuvastatin (a statin used to lower cholesterol)
- carbamazepine (used to treat epilepsy and control fits or convulsions)
- phenobarbital (used to treat epilepsy and control fits or convulsions)
- phenytoin (used to treat epilepsy and control fits or convulsions)
- St John's wort (*Hypericum perforatum*), a herbal product

It is currently unknown if OMJJARA could reduce the effectiveness of oral or other contraceptives, therefore it is recommended to add a barrier method during treatment and for at least 1 week after taking your last dose of OMJJARA.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OMJJARA.**

### 4. How do I take OMJJARA?

**How much to take**

- The recommended dose of OMJJARA is 200 mg taken by mouth once daily, with or without food.

You will have blood tests before you take this medicine and while you are taking it, to monitor your progress.

If you get certain side effects (such as abnormal bleeding or bruising, diarrhoea or nausea) while you are taking OMJJARA your doctor may recommend a lower dose, or pause or stop your treatment.

Your doctor may recommend a different dose if you have problems with your liver.

**When to take OMJJARA**

- Take your tablet about the same time once every day.
- Take exactly as your healthcare provider tells you to take it. Check with your doctor or pharmacist if you are not sure.

**If you forget to take OMJJARA**

OMJJARA should be used regularly at the same time each day. Do not take an extra dose if you miss a dose. Take your next dose at its scheduled time.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

**If you take too much OMJJARA**

If you think that you have used too much OMJJARA, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while taking OMJJARA?

**Things you should do**

- Always take this medicine exactly as your doctor or pharmacist has told you

**Call your doctor straight away if you:**

- are pregnant, think you may be pregnant or are planning to have a baby.
- are breastfeeding or intend to breastfeed.

Remind any doctor, dentist or pharmacist you visit that you are using OMJJARA.

**Things you should not do**

- Do not stop taking OMJJARA unless your doctor tells you to.
- Do not start a new medicine without checking first with the doctor who prescribed OMJJARA.

The following has been observed in another similar type of medicine used for the treatment of rheumatoid arthritis: heart problems, blood clots and cancer.

## Talk to your doctor or pharmacist before or during treatment:

- if you are older than 65. Patients aged 65 years and older may be at increased risk of heart problems including heart attack and some types of cancer.
- if you have or have had heart problems.
- if you have or have had cancer.
- if you are a smoker or have smoked in the past.
- if you have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) or if you have an increased risk of developing this, for example if:
  - you had recent major surgery.
  - you use hormonal contraceptives/hormonal replacement therapy.
  - you or a close relative have been diagnosed with a blood clotting disorder.

## Tell your doctor immediately if you get:

- sudden shortness of breath or difficulty breathing.
- chest pain or pain in upper back.
- swelling of the leg or arm.
- leg pain or tenderness.
- redness or discolouration in the leg or arm.

These can be signs of blood clots in the veins.

- if you notice any new growths on the skin or changes in existing growths. Your doctor may recommend that you have regular skin examinations while taking OMJJARA.

Your doctor will discuss with you if OMJJARA is appropriate for you.

## Driving or using machines

### Be careful before you drive or use any machines or tools until you know how OMJJARA affects you.

OMJJARA may make you feel dizzy or have blurred vision and therefore influence your ability to drive and use machines. Observe caution when driving or using machines.

## Looking after your medicine

- Keep your tablets in the bottle with the desiccant until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

## Keep it where young children cannot reach it.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

| Less serious side effects                                                                                                                                                                                                                                                                                               | What to do                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>Stomach or bowel problems:</b> <ul style="list-style-type: none"><li>• diarrhoea</li><li>• stomach ache (<i>abdominal pain</i>)</li><li>• constipation</li><li>• vomiting</li><li>• feeling sick (<i>nausea</i>)</li></ul>                                                                                           | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |
| <b>Nutrition problems:</b> <ul style="list-style-type: none"><li>• vitamin B1 (<i>thiamine</i>) deficiency which can cause loss of appetite, lack of energy, irritability</li></ul>                                                                                                                                     |                                                                                                    |
| <b>Nervous system problems:</b> <ul style="list-style-type: none"><li>• dizziness</li><li>• headache</li><li>• fainting (<i>syncope</i>)</li><li>• numbness, tingling or weakness of the arms, hands, legs or feet (<i>peripheral neuropathy</i>)</li><li>• abnormal tingling sensation (<i>paraesthesia</i>)</li></ul> |                                                                                                    |
| <b>Eye problems:</b> <ul style="list-style-type: none"><li>• blurred vision</li></ul>                                                                                                                                                                                                                                   |                                                                                                    |
| <b>Ear problems:</b> <ul style="list-style-type: none"><li>• spinning sensation (<i>vertigo</i>)</li></ul>                                                                                                                                                                                                              |                                                                                                    |
| <b>General disorders:</b> <ul style="list-style-type: none"><li>• feeling weak (<i>asthenia</i>)</li><li>• tiredness (<i>fatigue</i>)</li><li>• fever (<i>pyrexia</i>)</li></ul>                                                                                                                                        |                                                                                                    |
| <b>Blood vessel problems:</b> <ul style="list-style-type: none"><li>• low blood pressure which can cause light-headedness on standing up (<i>hypotension</i>)</li><li>• localised bleeding under the skin (<i>haematoma</i>)</li><li>• sudden reddening of the face, neck or upper chest (<i>flushing</i>)</li></ul>    |                                                                                                    |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <p><b>Respiratory problems:</b></p> <ul style="list-style-type: none"> <li>cough</li> </ul> <p><b>Musculoskeletal problems:</b></p> <ul style="list-style-type: none"> <li>joint pain (<i>arthralgia</i>)</li> <li>pain in limbs, hands or feet</li> </ul> <p><b>Injury:</b></p> <ul style="list-style-type: none"> <li>bruising (<i>contusion</i>)</li> </ul> <p><b>Skin problems:</b></p> <ul style="list-style-type: none"> <li>rash</li> </ul> |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

### Serious side effects

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | What to do                                                                                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Infections:</b></p> <ul style="list-style-type: none"> <li>infections – signs may include fever, chills, cough, breathing problems, diarrhoea, vomiting, pain or burning feeling when passing urine</li> </ul> <p><b>Change in blood test results:</b></p> <ul style="list-style-type: none"> <li>low blood platelet count (<i>thrombocytopenia</i>) which can result in bruising or bleeding for longer than usual if you hurt yourself</li> <li>low levels of a type of white blood cells (<i>neutropenia</i>) which can increase your risk of infection</li> <li>changes in blood test results (<i>alanine aminotransferase increased and aspartate aminotransferase increased</i>). These may be signs of liver problems.</li> </ul> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

### Other side effects reported (frequency not known)

- allergic reactions (*hypersensitivity*)

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What OMJJARA contains

|                                                 |                                                                                                                                                                                                                                                                               |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Active ingredient (main ingredient)</b>      | momelotinib                                                                                                                                                                                                                                                                   |
| <b>Other ingredients (inactive ingredients)</b> | microcrystalline cellulose<br>lactose monohydrate<br>sodium starch glycolate (type A)<br>magnesium stearate<br>colloidal anhydrous silica<br>propyl gallate<br>polyvinyl alcohol<br>macrogol 3350<br>titanium dioxide<br>purified talc<br>iron oxide yellow<br>iron oxide red |
| <b>Potential allergens</b>                      | lactose monohydrate                                                                                                                                                                                                                                                           |

**Do not take this medicine if you are allergic to any of these ingredients.**

### What OMJJARA looks like

#### OMJJARA 100 mg film-coated tablets

Brown, round tablets, with an underlined “M” debossed on one side and “100” on the other side.

(AUST R 442230)

#### OMJJARA 150 mg film-coated tablets

Brown, triangle shaped tablets, with an underlined “M” debossed on one side and “150” on the other side.

(AUST R 442231)

#### OMJJARA 200 mg film-coated tablets

Brown, capsule shaped tablets, with an underlined “M” debossed on one side and “200” on the other side.

(AUST R 442232)

### Who distributes OMJJARA

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

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