

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

Omjjara 100 mg

Each tablet contains:

momelotinib (as dihydrochloride monohydrate) – 100 mg

Omjjara 150 mg

Each tablet contains:

momelotinib (as dihydrochloride monohydrate) – 150 mg

Omjjara 200 mg

Each tablet contains:

momelotinib (as dihydrochloride monohydrate) – 200 mg

For the list of inactive and allergenic ingredients in the preparation, see in section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Additional information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Omjjara is a kinase inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

Therapeutic group: Protein kinase inhibitors.

How does Omjjara work?

An enlarged spleen is one of the characteristics of myelofibrosis. Myelofibrosis is a disorder of the bone marrow, in which the marrow is replaced by scar tissue. Myelofibrosis is classified as either:

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

The abnormal marrow can no longer produce enough normal blood cells and as a result, the spleen becomes significantly enlarged. Omjjara blocks the action of certain proteins, called Janus kinases (JAK1, JAK2) and activin A

receptor type 1 (ACVR1), preventing the overproduction of cytokines and reducing inflammation. By doing so, Omjjara relieves the enlarged spleen, anemia and symptoms such as fever, night sweats, bone pain and weight loss caused by myelofibrosis.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (listed in section 6 – “Additional information”). If you are uncertain, **do not take Omjjara before** checking with the physician.
- you are pregnant or breast-feeding.

Special warnings regarding use of the medicine

Before taking Omjjara or during the course of treatment with Omjjara, tell the physician if:

- you have an **infection** or have frequent infections – signs of an infection may include fever, chills, cough, breathing problems, diarrhea, vomiting, pain or burning feeling when passing urine.
- you have had hepatitis B for a long time (chronic), as hepatitis B may become active again.
- you have unusual bleeding or bruising under the skin, longer than usual bleeding after your blood has been drawn, or bleeding from the gums – these may be signs of low levels of blood platelets (components that help the blood to clot), also called thrombocytopenia.
- you have any **liver problems**. The physician may need to prescribe a lower dosage of 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 the physician before or during treatment if:

- you are older than 65 years. Patients aged 65 years and older may be at increased risk of heart problems, including heart attack, and some types of cancer.
- you have or have had heart problems.
- you have or have had cancer.
- you are a smoker or have smoked in the past.
- you have previously had blood clots in the veins of the 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 or hormonal replacement therapy.
 - you or a close relative has been diagnosed with a blood clotting disorder.

Tell the physician immediately if you get:

- sudden shortness of breath or difficulty breathing.

- chest pain or pain in the upper back.
- swelling of the leg or arm.
- leg pain or tenderness.
- redness or discoloration in the leg or arm.

These can be symptoms of blood clots in the veins.

- If you notice new growths on the skin or changes in existing growths. The physician may recommend that you have regular skin examinations while taking Omjjara.

Tests and follow-up

Before and during treatment, the physician will carry out blood tests to check your blood cell levels (red blood cells, white blood cells and platelets) and your liver function. The physician may adjust the dosage or stop treatment based on the results of the blood tests.

Children and adolescents

Omjjara should not be given to children and adolescents under 18 years of age, because the safety and efficacy of this medicine have not been studied in this age group.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. This is because Omjjara can affect the way some other medicines work. Also, some other medicines can affect the way Omjjara works.

It is particularly important that you mention any medicine containing any of the following active ingredients, as the physician may need to adjust the dosage of Omjjara or of the other medicine.

The following medicine may increase the risk of side effects with Omjjara:

- ciclosporin (used to prevent transplant rejection).

The following medicines may reduce the effectiveness of Omjjara:

- 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)
- *Hypericum perforatum* (St. John's wort), a herbal product.

Omjjara may affect other medicines:

- rosuvastatin (a statin used to lower cholesterol)
- sulfasalazine (used to treat rheumatoid arthritis)
- metformin (used to lower blood sugar levels)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle spasms)
- cyclophosphamide (used to treat cancer).

Use of the medicine and food

Omjjara can be taken with or without food.

Pregnancy, breast-feeding and fertility

Pregnancy:

Omjjara must not be used during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, do not take this medicine, as it could harm your baby. Consult the physician.

If you are a woman who could become pregnant, you must use highly effective **contraceptives** while you are taking Omjjara and you must continue to use highly effective contraceptives for **at least one week** after taking your last dose. It is currently unknown if Omjjara could reduce the effectiveness of hormonal contraceptives; therefore, it is recommended to add a contraceptive barrier method during treatment and for **at least one week** after taking the last dose of Omjjara. The physician may ask you to take a pregnancy test before starting treatment, to confirm that you are not pregnant.

If you become pregnant while taking Omjjara, **contact the physician immediately.**

Breast-feeding:

Omjjara must not be used during breast-feeding. It is not known if it passes into breast milk. A risk to the breast-fed child cannot be excluded.

Tell the physician if you are breast-feeding before taking the medicine.

Fertility:

It is unknown if Omjjara affects male or female fertility in humans. Omjjara had effects on fertility in animals. If you or your partner are planning to have a baby, ask the physician for advice before or while taking this medicine.

Driving and using machinery

Omjjara may have a minor influence on the ability to drive and use machines, dizziness or blurred vision may occur. If you feel dizzy or have blurred vision, do not drive or operate machines until these side effects have gone away.

Important information about some of the ingredients of the medicine

Omjjara contains lactose and sodium

Omjjara contains lactose (milk sugar). If you have been told by the physician that you have an intolerance to some sugars, contact the physician before taking this the medicine.

This preparation contains less than 1 mmol (23 mg) sodium per tablet, namely, it is considered a “sodium-free” preparation.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician’s instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the physician only.

Recommended dosage

The usual dosage for Omjjara is generally: 200 mg, taken by swallowing once a day.

The physician may recommend a lower dosage if you have problems with your liver.

If you get certain side effects (such as abnormal bleeding or bruising, diarrhea or nausea) while you are taking Omjjara, the physician may recommend a lower dosage, or pause or stop your treatment (see section 4 – “Side effects”).

How to take the medicine

Take Omjjara every day at the same time, with or without food.

Crushing/halving/chewing

There is no data regarding crushing/halving/chewing.

How long to take the medicine

Continue taking Omjjara for as long as the physician tells you to. This is a long-term treatment.

The physician will regularly monitor your condition to make sure that the treatment is having the desired effect.

If you have questions about how long to take Omjjara, talk to the physician.

If you accidentally took a higher dosage

If you accidentally take more Omjjara than prescribed for you by the physician, **contact the physician** immediately.

If a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

Take the next dose at the usual time on the next day. Do not take a double dose to compensate for a forgotten dose.

If you stopped taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician.

Do not exceed the recommended dosage.

Adhere to the treatment regimen as recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Omjjara may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Talk to the physician if you get any side effects that concern you.

Serious side effects

Some side effects could be serious. Seek medical help immediately before taking the next scheduled dose, if you experience the following serious side effects:

Very common side effects

These may occur in **more than 1 in 10** people:

- infection – signs or symptoms may include fever, chills, cough, breathing problems, diarrhea, vomiting, pain or burning when passing urine
- low blood platelet count (thrombocytopenia), which can result in bruising or bleeding for longer than usual if you hurt yourself.

Other side effects

Other possible side effects include the following listed below:

Very common side effects

These may occur in **more than 1 in 10** people:

- dizziness
- headache
- cough
- diarrhea
- feeling sick (nausea)
- stomachache (abdominal pain)
- feeling weak (asthenia)
- tiredness (fatigue).

Common side effects

These may occur in **up to 1 in 10** people:

- low level of a type of white blood cells (neutropenia), which can increase your risk of infection
- vitamin B1 (thiamine) deficiency, which may cause loss of appetite, lack of energy or irritability
- numbness, tingling or weakness of the arms, hands, legs or feet (peripheral neuropathy)
- abnormal tingling sensation (paresthesia)
- fainting (syncope)
- spinning sensation (vertigo)
- blurred vision
- sudden reddening of the face, neck or upper chest (flushing)
- localized bleeding under the skin (hematoma)
- low blood pressure, which can cause light-headedness when you stand up (hypotension)
- constipation
- vomiting
- rash (redness, swelling or pain of the skin)
- joint pain (arthralgia)
- pain in limbs, hands or feet
- fever (pyrexia)
- changes in blood test results (alanine aminotransferase increased and aspartate aminotransferase increased). These may be signs of liver problems
- bruising (contusion).

If a side effect occurs, if one of the side effects worsens or becomes troublesome, or if you suffer from side effects not mentioned in the leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking the link “Report side effects of drug treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 30°C.
- Store in the original bottle to protect from moisture. Do not remove the desiccant from the bottle. Do not swallow the desiccant.
- Do not discard medicines in the wastewater or household waste. Consult the pharmacist about how to dispose of medicines no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:

Tablet:

Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, magnesium stearate, silica colloidal anhydrous, and propyl gallate.

Coating:

Opadry II brown containing: polyvinyl alcohol, macrogol, titanium dioxide, talc, yellow iron oxide and red iron oxide.

See in section 2 – “Omjjara contains lactose and sodium.”

- What the medicine looks like and the contents of the package:

Omjjara 100 mg film-coated tablets are round-shaped brown tablets with an underlined “M” debossed on one side and “100” on the other side.

Omjjara 150 mg film-coated tablets are triangular-shaped brown tablets with an underlined “M” debossed on one side and “150” on the other side.

Omjjara 200 mg film-coated tablets are capsule-shaped brown tablets with an underlined “M” debossed on one side and “200” on the other side.

Omjjara film-coated tablets come in a white bottle with a seal and a child-resistant cap.

Each bottle contains 30 tablets, a silica gel desiccant and a polyester coil, and is packaged in a carton box.

Instructions for opening the bottle: To remove the cap, press down while simultaneously turning left (counter-clockwise).

Instructions for closing the bottle: Place the cap on the opening of the bottle and turn right (clockwise) until fully closed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
 - Omjjara 100 mg: 178-51-38144-99
 - Omjjara 150 mg: 178-52-38145-99
 - Omjjara 200 mg: 178-53-38146-99

Revised in March 2025

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Omjjara PT V2A