Package leaflet: Information for the patient

Omjjara 100 mg film-coated tablets
Omjjara 150 mg film-coated tablets
Omjjara 200 mg film-coated tablets
momelotinib

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Omjjara is and what it is used for
2. What you need to know before you take Omjjara
3. How to take Omjjara
4. Possible side effects
5. How to store Omjjara
6. Contents of the pack and other information

1. What Omjjara is and what it is used for

Omjjara contains the active substance momelotinib. Momelotinib is a type of medicine known as a *protein kinase inhibitor*.

Omjjara is used to treat enlarged spleen or other disease related symptoms in adult patients with myelofibrosis, a rare form of blood cancer, and moderate to severe anaemia.

In myelofibrosis, bone marrow is replaced by scar tissue and 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 polycythaemia vera myelofibrosis) or blood platelets, which help the blood to clot (post essential thrombocythemia myelofibrosis).

How Omjjara works

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. 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 over production of cytokines and reducing inflammation. By doing so, Omjjara relieves the enlarged spleen, anaemia, and symptoms such as fever, night sweats, bone pain and weight loss caused by myelofibrosis.

2. What you need to know before you take Omjjara

Do not take Omjjara
- if you are allergic to momelotinib or any of the other ingredients of this medicine (listed in section 6). If you are not sure whether this applies to you, **do not take Omjjara** until you have checked with your doctor.
- if you are pregnant or breast-feeding.

Warnings and precautions
Tell your doctor
Talk to your doctor, pharmacist, or nurse before taking Omjjara or during your treatment with Omjjara:
- if you have an **infection** or have frequent infections — signs of an infection may include fever, chills, cough, breathing problems, diarrhoea, vomiting, pain or burning feeling when passing urine.
- if you have had **hepatitis B** for a long time (chronic) as hepatitis B may become active again.
- 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 low levels of blood platelets (components that help the blood to clot), also called thrombocytopenia.
- if you have any **liver problems**. Your doctor may need to prescribe a lower dose 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 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.

Blood tests
Before and during treatment, your doctor will carry out 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.

Children and adolescents
Omjjara should not be given to children under 18 years of age, because this medicine has not been studied in this age group.

Other medicines and Omjjara
Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines. This includes herbal preparations and medicines without a prescription. 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 medicines containing any of the following active substances, as your doctor may need to adjust the dose of Omjjara or the other medicine.

The following may increase the risk of side effects with Omjjara:
- ciclosporin (used to prevent transplant rejection)

The following 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)
- St John's wort (Hypericum perforatum), 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)
- tizanadine (used to treat muscle spasms)
- cyclophosphamide (used to treat cancer)

Pregnancy, breast-feeding and fertility
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. Talk to your doctor for advice.

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. It is currently unknown if Omjjara could reduce the effectiveness of hormonal 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. Your doctor may ask you to take a pregnancy test before starting your treatment, to confirm that you are not pregnant.

If you become pregnant while you are taking Omjjara, **contact your doctor immediately.**

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

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 your doctor for advice before, or while taking, this medicine.

Driving and using machines
Omjjara may have side effects that affect your ability to drive. If you feel dizzy or have blurred vision, do not drive or operate machines until these side effects have gone away.

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Omjjara

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
The recommended starting dose of Omjjara is 200 mg taken by mouth once daily.

Your doctor may recommend a lower dose if you have problems with your liver.
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 (see section 4).

How to take it
Take Omjjara every day at the same time, with or without meals.

How long to take it
Continue taking Omjjara for as long as your doctor tells you to. This is a long-term treatment.

Your doctor 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 your doctor.

If you take more Omjjara than you should
If you accidentally take more Omjjara than your doctor prescribed, **contact your doctor** immediately.

If you forget to take Omjjara
Simply take your next dose at the scheduled time the next day. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Omjjara
Do not stop taking Omjjara unless you have agreed this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Talk to your doctor, pharmacist or nurse 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

May affect **more than 1 in 10** people:

- infections — signs or symptoms may include fever, chills, cough, breathing problems, diarrhoea, vomiting, pain or burning feeling 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

May affect **more than 1 in 10** people:

- dizziness
- headache
- cough
- diarrhoea
- feeling sick (*nausea*)
- stomach ache (*abdominal pain*)
- feeling weak (*asthenia*)
- tiredness (*fatigue*)

Common side effects

May affect **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 can cause loss of appetite, lack of energy, irritability
- numbness, tingling or weakness of the arms, hands, legs or feet (*peripheral neuropathy*)
- abnormal tingling sensation (*paraesthesia*)
- fainting (*syncope*)
- spinning sensation (*vertigo*)
- blurred vision
- sudden reddening of the face, neck or upper chest (*flushing*)
- localised bleeding under the skin (*haematoma*)
- 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*)

Other side effects reported (frequency not known)

- allergic reactions (*hypersensitivity*)

Tell your doctor, pharmacist or nurse if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side

effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Omjjara

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and carton after "EXP". The expiry date refers to the last day of that month.

Store in the original bottle in order to protect from moisture. Do not remove the desiccant. Do not swallow the desiccant. This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Omjjara contains

The active substance is momelotinib.

- Each 100 mg film-coated tablet contains momelotinib dihydrochloride monohydrate equivalent to 100 mg of momelotinib.
- Each 150 mg film-coated tablet contains momelotinib dihydrochloride monohydrate equivalent to 150 mg of momelotinib.
- Each 200 mg film-coated tablet contains momelotinib dihydrochloride monohydrate equivalent to 200 mg of momelotinib.
- The other excipients are:
  Tablet core: microcrystalline cellulose, lactose monohydrate, sodium starch glycolate (type A), magnesium stearate, silica colloidal anhydrous, and propyl gallate.
  Tablet coating: Opadry II brown containing polyvinyl alcohol, macrogols, titanium dioxide (E171), talc, iron oxide yellow (E172) and iron oxide red (E172).

See section 2 Omjjara contains lactose and sodium.

What Omjjara looks like and contents of the pack

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 triangle-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 are supplied in a white bottle with a seal and a child-resistant cap. Each bottle contains 30 tablets, a silica gel desiccant, a polyester coil, and is packed in a cardboard carton.

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name **Omjjara 100 mg film coated tablets**
Omjjara 150 mg film-coated tablets
Omjjara 200 mg film-coated tablets

Reference number 19494/0318

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