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SCIENCE MEDICINES HEALTH

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Omjjara (*momelotinib*)

An overview of Omjjara and why it is authorised in the EU

What is Omjjara and what is it used for?

Omjjara is a medicine used to treat splenomegaly (enlarged spleen) or other disease-related symptoms in adults who have myelofibrosis and moderate to severe anaemia (low levels of red blood cells). Myelofibrosis is a disease in which the bone marrow becomes very dense and rigid and produces abnormal, immature blood cells.

Omjjara is used both in patients who have never used medicines known as Janus kinase inhibitors (JAKi) before and in those who have been treated with the JAKi ruxolitinib. Omjjara can be used in three types of the disease:

- primary myelofibrosis (also known as chronic idiopathic myelofibrosis), where the cause of the disease is unknown;
- post-polycythaemia vera myelofibrosis, where the disease is linked to an overproduction of red blood cells;
- post-essential thrombocythaemia myelofibrosis, where the disease is linked to an overproduction of platelets (components that help the blood to clot).

These diseases are rare, and Omjjara was designated an 'orphan medicine' (a medicine used in rare diseases). Further information on the orphan designations can be found on the EMA website ([post-polycythaemia vera myelofibrosis](#), [post-essential thrombocythaemia myelofibrosis](#), [primary myelofibrosis](#): 05 August 2011).

Omjjara contains the active substance momelotinib.

How is Omjjara used?

The medicine can only be obtained with a prescription and treatment must be started and monitored by doctors experienced in the use of cancer medicines. Omjjara is available as a tablet to be taken by mouth once daily.

The doctor may reduce the dose, interrupt treatment or stop it altogether if the patient has certain side effects. Treatment should continue for as long as the patient benefits from it.

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For more information about using Omjjara, see the package leaflet or contact your doctor or pharmacist.

How does Omjjara work?

The active substance in Omjjara, momelotinib, works by blocking a group of enzymes (proteins) known as Janus kinases (JAKs), which are involved in the production and growth of blood cells. In myelofibrosis, there is too much JAK activity, leading to the abnormal production of blood cells and inflammation. As a result, scar tissue replaces the bone marrow causing blood cells to be produced in other organs such as the liver and spleen instead of the bone marrow. This manifests as splenomegaly and reduction of the levels of healthy blood cells, including red blood cells.

By blocking JAKs, momelotinib reduces the inflammation resulting from abnormal production of blood cells which relieves splenomegaly and symptoms caused by myelofibrosis. Momelotinib also blocks a protein involved in regulating iron levels in the body, known as ACVR1, which allows more iron to be available for the production of red blood cells and may result in improvement of anaemia, including the need for transfusion of red blood cells.

What benefits of Omjjara have been shown in studies?

In a main study involving 195 patients with myelofibrosis associated with moderate to severe anaemia who had already been treated with the JAKi ruxolitinib, Omjjara was effective at improving symptoms of myelofibrosis and at reducing the size of patients' spleen after 24 weeks of treatment. Around 25% of those given Omjjara (32 out of 130) had at least a 50% reduction in symptoms of myelofibrosis over the last 28 days of treatment, compared to 9% of patients given another medicine, danazol (6 out of 65). Around 22% of patients given Omjjara (29 out of 130) had at least a 35% reduction in spleen size compared to around 3% of patients given danazol (2 out of 65).

In this study, a higher proportion of patients treated with Omjjara were transfusion independent after 24 weeks of treatment, meaning they did not need a transfusion of red blood cells and had haemoglobin (the protein in red blood cells that carries oxygen around the body) levels of at least 8 g/dL. In the 12 weeks prior to week 24, 30% of those given Omjjara (39 out of 130) were transfusion independent compared to 20% with danazol (13 out of 65).

In a second study, involving 181 patients with myelofibrosis associated with moderate to severe anaemia who had not been treated with a JAKi before, after 24 weeks of treatment around 31% of patients given Omjjara (27 out of 86) had at least a 35% reduction in spleen size compared to around 33% with ruxolitinib (31 out of 95). Altogether, 25% of those given Omjjara (21 out of 86) had at least a 50% reduction in symptoms of myelofibrosis over the last 28 days of treatment, compared to 36% with ruxolitinib (34 out of 95).

What are the risks associated with Omjjara?

For the full list of side effects and restrictions with Omjjara, see the package leaflet.

The most common side effects with Omjjara (which may affect more than 1 in 10 people) include diarrhoea, thrombocytopenia (low levels of blood platelets), nausea (feeling sick), headache, dizziness, tiredness, weakness, abdominal (belly) pain and cough.

The most common serious side effect was thrombocytopenia.

Omjjara must not be used in pregnancy and while breastfeeding.

Why is Omjjara authorised in the EU?

The European Medicines Agency decided that Omjjara's benefits are greater than its risks and it can be authorised for use in the EU.

Omjjara has been shown to improve symptoms of myelofibrosis in patients with moderate to severe anaemia who have not been treated with a JAKi or who have been treated with the JAKi ruxolitinib. These include symptoms of splenomegaly (such as pain under ribs on the left side of the body and early satiety), anaemia, including the need for transfusions, and other symptoms of myelofibrosis (such as tiredness, itching and bone pain). The Agency therefore considered that Omjjara addressed a medical need in patients with myelofibrosis, particularly in those with moderate to severe anaemia who initially manifest or continue to experience symptoms of myelofibrosis despite previous treatment with the JAKi ruxolitinib. Overall, the safety profile of Omjjara was considered acceptable.

What measures are being taken to ensure the safe and effective use of Omjjara?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Omjjara have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Omjjara are continuously monitored. Suspected side effects reported with Omjjara are carefully evaluated and any necessary action taken to protect patients.

Other information about Omjjara

Omjjara received a marketing authorisation valid throughout the EU on 25 January 2024.

Further information on Omjjara can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/omjjara.

This overview was last updated in 01/2024.