Prescribing information – Northern Ireland

Omjjara ▼ (momelotinib) 100 mg, 150 mg and 200 mg film-coated tablets Prescribing Information

Please consult the full Summary of Product Characteristics for Northern Ireland (SmPC NI) before prescribing Omjjara.

Presentation: Omjjara 100 mg, 150 mg and 200 mg film coated tablets containing momelotinib dihydrochloride monohydrate equivalent to 100mg, 150 mg or 200 mg momelotinib and lactose monohydrate 50.8mg, 76.1 mg or 101.5 mg respectively per tablet. *Omjjara 100 mg tablets*: brown, round tablets, of approximately 8.7 mm diameter, with an underlined "M" debossed on one side and "100" on the other side. *Omjjara 150 mg tablets:* brown, triangle shaped tablets, approximately 10.5 x 10.9 mm, with an underlined "M" debossed on one side and "150" on the other side. *Omjjara 200 mg tablets:* brown, capsule shaped tablets, approximately 7.3 x 15.4 mm, with an underlined "M" debossed on one side and "200" on the other side.

Indication: For the treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

Dosage and administration: Treatment should be initiated and monitored by physicians experienced in the use of anti-cancer medicinal products. Should not be used in combination with other JAK inhibitors**.** Complete blood cell count (including platelet count) and liver function tests must be performed before initiating treatment, periodically during treatment, and as clinically indicated. The recommended dose is 200 mg taken orally once daily, with or without food. The recommended starting dose is 150 mg once daily in patients with severe hepatic impairment (Child-Pugh Class C). If a dose is missed, the next scheduled dose should be taken the following day. Two doses should not be taken at the same time to make up for the missed dose Treatment may be continued for as long as the benefit-risk remains positive for patients, as assessed by the treating physician.

Special populations: *Elderly:* No dose adjustment required in patients ≥65 years. *Renal impairment:* No dose adjustment required for patients with renal impairment (>15 mL/min); no data in patients with end-stage renal disease. *Hepatic impairment*: No dose adjustment recommended in patients with mild or moderate hepatic impairment; recommended starting dose of Omjjara is 150 mg once daily in patients with severe hepatic impairment (Child-Pugh Class C). *Paediatrics*: Safety and efficacy not established in patients <18 years.

Dose modifications/discontinuations: Omjjara SmPC must be consulted for detailed dose modification and discontinuations for haematologic and non-hematologic toxicity. Omjjara should be discontinued in patients unable to tolerate 100mg once daily. Dose modification/ discontinuation for: *Thrombocytopenia* (platelet count decreases to <50 × 10^9/L to <20 × 10^9/L, dependent on baseline platelet count). *Neutropenia* (absolute neutrophil count <0.5 × 10^9/L). *Hepatotoxicity* (ALT and/or AST >5 × ULN [or >5 × baseline, if baseline is abnormal] and/or total bilirubin >2 × ULN [or >2 × baseline, if baseline is abnormal]). *Other non-haematologic adverse events* grade 3 or higher/ grade 2 or higher; *bleeding*.

Contraindications: Hypersensitivity to the active substance or to any of the excipients; see SmPC for full details. Pregnancy and breast-feeding.

Warnings and precautions:
Infections: Infections (serious, fatal, bacterial and viral, including COVID-19) have occurred in patients treated with Omjjara and it should not be initiated in patients with active infections. Physicians should carefully observe patients during treatment for signs and symptoms of infection (including but not limited to fever, cough, diarrhoea, vomiting, nausea, and pain upon urination) and initiate appropriate treatment promptly. *Hepatitis B reactivation*: Increases in hepatitis B viral load (HBV-DNA titer) with or without associated elevations in ALT or AST were reported in patients with chronic hepatitis B virus (HBV) taking Omjjara. Patients with chronic HBV infection who receive Omjjara should have their chronic HBV infection treated and monitored according to clinical HBV guidelines. *Thrombocytopenia and neutropenia*: New onset of grade ≥3 thrombocytopenia and neutropenia was observed in patients treated with Omjjara. Dose interruption or reduction may be required. *Hepatic monitoring*: Liver function tests should be obtained before initiating Omjjara. If increases in ALT, AST and/or bilirubin related to treatment are suspected, dose reduction or interruption may be required. *Major adverse cardiovascular events (MACE):* Events of MACE have been reported in patients receiving Omjjara, however a causal relationship has not been established. Consider the benefits and risks of Omjjara before initiating or continuing therapy particularly in patients ≥65 years of age, current or past long-time smokers, have a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors. *Thrombosis*: Events of deep venous thrombosis and pulmonary embolism have been reported in patients receiving Omjjara. Consider the benefits and risks for the patient before initiating or continuing Omjjara, particularly in patients with cardiovascular risk factors. *Second primary malignancies*: Lymphoma and other malignancies have been reported in patients receiving JAK inhibitors, including Omjjara. A causal association has not been established. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take Omjjara.

Interactions: Effect of other medicinal products on Omjjara: Omjjara undergoes metabolism though multiple CYP enzymes (including CYP3A4, CYP2C8, CYP2C9, CYP2C19, and CYP1A2) and aldehyde oxidase, with CYP3A4 having the greatest contribution. *Strong CYP3A4 inducers:* Co-administration of strong CYP3A4 inducers (including but not limited to carbamazepine, phenobarbital, phenytoin, and St John's wort [Hypericum perforatum]) may lead to decreased momelotinib exposure and a risk for reduced efficacy. Additional monitoring of the clinical signs and symptoms of myelofibrosis recommended. Omjjara can be co-administered with rifampicin without a dose modification. *Transporters:* Caution and monitoring for adverse reactions is advised with concomitant use of OATP1B1/1B3 inhibitors, including ciclosporin. Effect of Omjjara on other medicinal products: *Transporters:* Omjjara is an inhibitor of breast cancer resistance protein (BCRP) *in vitro*; monitor for adverse reactions with co-administration of sensitive BCRP substrates, including rosuvastatin and sulfasalazine. Omjjara may inhibit P-gp in the gut and increase exposure to P-gp substrates, caution when administering with P-gp substrates with a narrow therapeutic index. Caution when administering with sensitive substrates of OCT1, MATE1 and MATE2-K (e.g. metformin). *CYP450 substrates:* Omjjara may induce CYP1A2 and CYP2B6 and may inhibit CYP2B6. Narrow therapeutic index or sensitive substrate medicinal products of CYP1A2 (e.g. theophylline, tizanidine) or CYP2B6 (e.g. cyclophosphamide) should be co-administered with caution. *Hormonal contraceptives:* The effectiveness of oral contraceptives co-administered with Omjjara may be reduced.
Fertility, pregnancy and lactation: *Women of childbearing potential (WOCBP)/Contraception:* WOCBP should be advised to avoid becoming pregnant whilst receiving Omjjara. Women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara. *Pregnancy:* Omjjara is contraindicated during pregnancy. If used during pregnancy, or if the patient becomes pregnant while on treatment, the patient should discontinue treatment and be advised of the potential hazard to the foetus. *Breast-feeding:* Contraindicated during breast-feeding. *Fertility:* No clinical data on human male or female fertility.

Effects on ability to drive and use machines: Omjjara may have a minor influence on the ability to drive and use machines, dizziness or blurred vision may occur. If dizziness or blurred vision occurs after taking Omjjara, patients should observe caution when driving or using machines.

Undesirable effects: The most common severe adverse reaction (Grade ≥3) was thrombocytopenia (11%). The most common adverse reaction leading to discontinuation of Omjjara was thrombocytopenia (2%). The most common adverse reaction requiring dosage reduction and/or treatment interruption was thrombocytopenia (7%). *Very Common (≥1/10):* thrombocytopenia, dizziness, headache, cough, diarrhoea, abdominal pain, nausea, asthenia, fatigue. *Common (≥1/100 to <1/10):* urinary tract infection, upper respiratory tract infection, pneumonia, nasopharyngitis, COVID 19, cystitis, bronchitis, oral herpes, sinusitis, herpes zoster, cellulitis, respiratory tract infection, sepsis, lower respiratory tract infection, oral candidiasis, skin infection, gastroenteritis, neutropenia, vitamin B1 deficiency, syncope, peripheral neuropathy, paraesthesia, blurred vision, vertigo, hypotension, haematoma, flushing, vomiting, constipation, arthralgia, pain in extremity, pyrexia, alanine transaminase (ALT) increased, aspartate transaminase (AST) increased, contusion. *Uncommon (≥1/1 000 to <1/100):* COVID 19 pneumonia. Refer to the Omjjara SmPC for a full list of adverse events.
Overdose: Refer to SmPC. **Legal Category:** POM.
Pack size:
30 x 100 mg film-coated tablet, £5,650
30 x 150 mg film-coated tablet, £5,650
30 x 200 mg film-coated tablet, £5,650
MA numbers:
EU/1/23/1782/001; EU/1/23/1782/002; EU/1/23/1782/003
MA Holder: GlaxoSmithKline Trading Services Limited 12 Riverwalk Citywest Business Campus Dublin 24 Ireland. *Full SmPC available from GSK Limited or from www.emcmedicines.com/en-GB/northernireland/.*
Date of preparation: February 2024 **PI Job Bag Number:** PI-12710

Adverse events should be reported. Reporting forms and information can be found at: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 or UKSafety@gsk.com