Prescribing information- Northern Ireland

▼JEMPERLI (dostarlimab) 500 mg concentrate for solution for infusion Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing JEMPERLI.

Presentation: Concentrate for solution for infusion. Each vial contains 500mg dostarlimab in 10 mL concentrate (50 mg/mL). Clear to slightly opalescent colourless to yellow solution, essentially free from visible particles.

Indication: JEMPERLI is indicated:

- in combination with carboplatin and paclitaxel for the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.
- as monotherapy for the treatment of adult patients with dMMR/MSI-H recurrent or advanced EC that has progressed on or following prior treatment with a platinum-containing regimen.

Dosage and administration: JEMPERLI *in combination with carboplatin and paclitaxel:* Recommended dose is 500mg dostarlimab every 3 weeks for 6 cycles followed by 1000mg every 6 weeks thereafter (cycle 7 onwards) until disease progression or unacceptable toxicity, or for a duration of up to 3 years. Administer JEMPERLI prior to carboplatin and paclitaxel on the same day. Refer to the SmPC for dosing of the combination products. JEMPERLI *monotherapy*: Recommended dose is 500 mg dostarlimab every 3 weeks for 4 cycles followed by 1000 mg every 6 weeks for all cycles thereafter (cycle 5 onwards), until disease progression or unacceptable toxicity.

JEMPERLI should be administered by intravenous infusion using an intravenous infusion pump over 30 minutes. JEMPERLI must not be administered as an intravenous push or bolus injection. Do not co-administer other medicinal products through the same infusion line. A 0.2 or 0.22 micron in-line polyethersulfone (PES) filter must be used during administration of JEMPERLI.
Special populations*: Elderly*: No dose adjustment recommended in patients ≥65 years; limited data in patients ≥75 years. *Renal impairment*: No dose adjustment recommended in mild or moderate renal impairment; limited data in patients with severe impairment or end-stage renal disease undergoing dialysis. *Hepatic impairment*: No dose adjustment recommended in patients with mild hepatic impairment, limited data in moderate hepatic impairment and no data in severe hepatic impairment. *Paediatrics*: Safety and efficacy not established in patients <18 years.
Dose modifications: No dose reductions of JEMPERLI are recommended. Permanently discontinue JEMPERLI for grade ≥2 myocarditis, severe neurological toxicity, recurrence or worsening hypophysitis or adrenal insufficiency while on adequate hormonal therapy; grade ≥3 hepatitis, nephritis, pneumonitis (or if grade 2 recurs), recurrence immune-related adverse reactions(irARs) after resolution to ≤ grade 1 and infusion-related reactions (or if grade 2 recurs with adequate premedication); grade 4 colitis, other irARs and confirmed exfoliative dermatologic conditions. See SmPC for full details.

Contraindications: Hypersensitivity to the active substance or to any of its excipients, see SmPC for full details.

Warnings and precautions (see SmPC for full details):

- IrARs, which may be severe or fatal, including the following but not limited to: immune-related pneumonitis, immune-related colitis, immune-related hepatitis, immune-related endocrinopathies, immune-related nephritis, immune-related rash and other exfoliative dermatologic adverse reactions, immune-related arthralgia, immune-related myocarditis, immune-related neurological toxicities, other irARs and solid organ transplant rejection. While irARs usually occur during treatment with PD-1/PD-L1 blocking antibodies, symptoms can also manifest after discontinuation of treatment. IrARs may occur in any organ or tissue and may affect more than one body system simultaneously. Monitor patients for signs and symptoms of irARs. Evaluate haematological and clinical chemistries, including liver, kidney and thyroid function, at baseline and periodically during treatment. Withhold or permanently discontinue JEMPERLI and administer corticosteroids or other appropriate therapy based on the severity of reaction. Upon improvement to Grade ≤1, initiate corticosteroid taper and continue for ≥1 month.
- Infusion-related reactions: Can be severe. Stop infusion and permanently discontinue grade ≥3. Grade 2 withhold dose and if resolved within 1 hour of stopping, restart at 50% of the original infusion rate, or restart when symptoms resolve with premedication.
- Transplant-related complications: Fatal and other serious complications can occur in patients who receive allogeneic haematopoetic stem cell transplantation before or after being treated with a PD-1/PD-L1–blocking antibody. Follow patients closely and intervene promptly. Consider benefits versus risks of PD1-blocking antibody therapy.

Interactions: No interaction studies have been performed. Monoclonal antibodies (mAb) such as JEMPERLIare not substrates for cytochrome P450 or active substance transporters. JEMPERLI is not a cytokine and is unlikely to be a cytokine modulator. Additionally, pharmacokinetic interaction of JEMPERLI with small molecule active substances is not expected. There is no evidence of interaction mediated by non-specific clearance of lysosome degradation for antibodies.

Fertility, pregnancy and lactation: *Fertility:* No clinical data on fertility. *Pregnancy:* No or limited clinical data on use in pregnant women. JEMPERLI can cause foetal harmful pharmacological effects when administered during pregnancy. JEMPERLI is not recommended during pregnancy and in women of childbearing potential (WOCBP) not using effective contraception. WOCBP must use effective contraception during treatment and until 4 months after the last dose. *Lactation:* Not recommended during breast-feeding and breast-feeding should be avoided for at least 4 months after the last dose of JEMPERLI.

Undesirable effects: JEMPERLI *in combination with chemotherapy*: Most common adverse reactions (ADRs) (>10%) were rash, rash maculopapular, hypothyroidism, transaminases increased, pyrexia and dry skin. JEMPERLI monotherapy: Most common ADRs in patients with advanced or recurrent solid tumours (> 10 %) were anaemia, nausea, diarrhoea, vomiting, arthralgia, pruritus, rash, pyrexia, aspartate aminotransferase increased and hypothyroidism. Most serious adverse reactions were irARs. JEMPERLI *in combination therapy AND* JEMPERLI *monotherapy: Very common (≥1/10):* hypothyroidism, rash, pyrexia, transaminases increased; *Common (≥1/100 to <1/10):* hyperthyroidism, adrenal insufficiency, pneumonitis, colitis; *Uncommon (≥1/1000 to <1/100):* thyroiditis, type 1 diabetes mellitus, uveitis, immune-mediated arthritis. JEMPERLI *in combination therapy only: Very common (≥1/10):* dry skin; *Uncommon (≥1/1000 to <1/100):* myasthenic syndrome, myocarditis, pancreatitis, immune mediated gastritis, vasculitis gastrointestinal, myositis, systemic inflammatory response syndrome. JEMPERLI *monotherapy only: Very common (≥1/10):* anaemia, diarrhoea, nausea, vomiting, pruritus, arthralgia; *Common (≥1/100 to <1/10):* pancreatitis, gastritis, hepatitis, myalgia, chills, infusion-related reaction; *Uncommon (≥1/1000 to <1/100):* hypophysitis, diabetic ketoacidosis, encephalitis, myasthenia gravis, oesophagitis, polymyalgia rheumatica, immune-mediated myositis, nephritis.

Refer to the SmPC for a full list of adverse events.
Overdose: Refer to SmPC.

Legal Category: POM.
Pack size: 1 vial of 500mg/10mL £5887.33
MA Number: EU/1/21/1538/001
MA Holder: GlaxoSmithKline (Ireland) Limited 12 Riverwalk Citywest Business Campus Dublin 24 Ireland *Full SmPC available from GSK Limited or from* https://www.emcmedicines.com/en-GB/northernireland/
Date of preparation: November 2023
PI Job Bag Number: PI-12428

Adverse events should be reported. Reporting forms and information can be found at: https://yellowcard.mhra.gov.uk/ (UK) or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to GSK: please call 0800 221 441 or email uksafety@gsk.com