Prescribing information- Northern Ireland

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

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

Presentation: Jemperli is a clear to slightly opalescent colourless to yellow solution, essentially free from visible particles. The concentrate for solution for infusion has a pH of approximately 6.0 and an osmolality of approximately 300 mOsm/kg. Each vial contains 10 mL concentrate for solution for infusion of 500 mg of dostarlimab.

Indication: Monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

Dosage and administration:

The recommended dose as monotherapy is 500 mg dostarlimab every 3 weeks for 4 cycles followed by 1000 mg every 6 weeks for all cycles thereafter.

- Dose 1 through Dose 4: 500 mg every 3 weeks
- Subsequent dosing beginning 3 weeks after Dose 4 (Dose 5 onwards): 1,000 mg every 6 weeks

JEMPERLI should be administered by intravenous infusion using an intravenous infusion pump over 30 minutes by a health care practitioner. JEMPERLI is compatible with an IV bag made of polyvinyl chloride (PVC) with or without di(2-ethylhexyl) phthalate (DEHP), ethylene vinyl acetate, polyethylene (PE), polypropylene (PP) or polyolefin blend (PP+PE), and a syringe made from PP. JEMPERLI must not be administered as an intravenous push or bolus injection. Do not co-administer other medicinal products through the same infusion line. Tubing should be made of PVC, platinum cured silicon or PP; fittings made from PVC or polycarbonate and needles made from stainless steel. A 0.2 or 0.22 micron in-line polyethersulfone (PES) filter must be used during administration of JEMPERLI. Treat patients until disease progression or unacceptable toxicity. Injection: 500 mg/10 mL (50 mg/mL) solution in a single-dose vial.

No dose reductions of JEMPERLI are recommended. In general, withhold JEMPERLI for severe (Grade 3) immune-mediated adverse reactions (refer to SmPC). Permanently discontinue JEMPERLI for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids

Contraindications: Hypersensitivity to the active substance or to any of the excipients: Trisodium citrate dihydrate, Citric acid monohydrate, L-arginine hydrochloride, Sodium chloride, Polysorbate 80.

Warnings and precautions:

- Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: Immune-related arthralgia, immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated nephritis with renal dysfunction, immune-mediated dermatologic adverse reactions, and solid organ transplant rejection. While immune-related adverse reactions usually occur during treatment with PD-1/PD-L1 blocking antibodies, symptoms can also manifest after discontinuation of treatment. Immune-related adverse reactions may occur in any organ or tissue and may affect more than one body system simultaneously. Monitor for signs and symptoms of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver enzymes, creatinine, and thyroid function, at baseline and periodically during treatment. Withhold or permanently discontinue JEMPERLI and administer corticosteroids or other appropriate therapy administered based on the severity of reaction.
- Infusion-related reactions: Interrupt, slow the rate of infusion, stop, or permanently discontinue JEMPERLI based on severity of reaction.
- Complications of allogeneic hematopoietic stem cell transplantation (HSCT): Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1–blocking antibody.
- Embryo-fetal toxicity: Can cause fetal harm. Advise women of childbearing potential of the potential risk to a fetus and to use effective contraception during treatment, and until 4 months after the last dose.

Interaction:
No interaction studies have been performed. Monoclonal antibodies (mAb) such as dostarlimab are not substrates for cytochrome P450 or active substance transporters. Dostarlimab is not a cytokine and is unlikely to be a cytokine modulator. Additionally, pharmacokinetic (PK) interaction of dostarlimab 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:* Not recommended for use during pregnancy and in women of childbearing potential not using contraception. Based on its mechanism of action, dostarlimab can cause foetal harmful pharmacological effects when administered during pregnancy. *Lactation:* Not recommended during breast-feeding and breast-feeding should be avoided for at least 4 months after the last dose of dostarlimab

Undesirable effects: Most common adverse reactions in patients with advanced or recurrent solid tumours (> 10 %) were anaemia, nausea, diarrhoea, vomiting, arthralgia, pruritus, rash, pyrexia and hypothyroidism. Most common Grade 3 or 4 were anaemia, nausea, vomiting, diarrhoea, rash, and transaminases increased.

Very common (≥1/10): Anaemia, hyperthyroidism, nausea, diarrhoea, vomiting, pruritus, rash, arthralgia, pyrexia

Common (≥1/100 to <1/10): Hyperthyroidism, adrenal insufficiency, pneumonitis, colitis, pancreatitis, myalgia, chills, infusion-related reaction

Uncommon grade 3 or 4 (≥1/1000 to <1/100): Adrenal insufficiency, hyperthyroidism, pneumonitis, pancreatitis, colitis, hepatitis, pruritus, arthralgia, pyrexia, Infusion-related reaction

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 www.medicines.org.uk*.

Date of preparation: May 2022

PI Job Bag Number: PI-8951

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