# Prescribing information

BLENREP▼ (belantamab mafodotin) 100 mg powder for concentrate for solution for infusion

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

**Presentation:** BLENREP is a white to yellow powder. One vial of powder contains 100 mg of belantamab mafodotin. After reconstitution, the solution contains 50 mg belantamab mafodotin per ml. Each vial also contains sodium citrate, citric acid, trehalose dihydrate, disodium edetate and polysorbate 80.
**Indication:** Monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.
**Dosage and administration:** The recommended dose is 2.5 mg/kg administered as an intravenous infusion once every 3 weeks, reconstituted and diluted prior to administration. BLENREP should be infused over a minimum of 30 minutes using an infusion set made of polyvinyl chloride or polyolefin. The dose (mg), total volume (mL) of solution required and the number of vials needed is based on patient's actual body weight (kg). Dose modifications may be implemented based on adverse reactions (refer to SmPC). No dose adjustment is required in the elderly. No dose adjustment is required in patients with mild o r moderate renal (eGFR ≥ 30 mL/min) and mild hepatic impairment.
**Contraindications:** Hypersensitivity to the active substance or to any of the excipients.

**Warnings and precautions:** Corneal adverse reactions have been reported with BLENREP (keratopathy or microcyst-like epithelial changes in corneal epithelium with or without changes in visual acuity, blurred vision, and dry eye symptoms). Ophthalmic examinations including assessment of visual acuity and slit lamp examination, should be performed at baseline, before the subsequent 3 treatment cycles and during treatment as clinically indicated. Patients should be advised to administer preservative-free artificial tears at least 4 times a day during treatment and should avoid using contact lenses until the end of treatment. Patients experiencing corneal adverse reactions may require dose modifications or treatment discontinuation based on severity of findings. Cases with changes in the subbasal nerve plexus of the cornea (e.g. nerve fibre fragmentation and loss of nerve fibres) resulting in hypoesthesia of the cornea. Corneal ulcers (ulcerative and infective keratitis) have been reported with BLENREP. Corneal ulcers should be managed promptly and treatment with BLENREP should be interrupted until the corneal ulcer has healed. Due to the risk of thrombocytopenic events, complete blood counts should be obtained at baseline and monitored during treatment. Patients on concomitant anticoagulant treatments or experiencing grade 3 or 4 thrombocytopenia may require more frequent monitoring and should be managed with a dose delay or dose reductions. Supportive therapy (e.g. platelet transfusions) should be provided according to standard medical practice. If Grade 2 or higher infusion-related reaction occurs, reduce infusion rate, interrupt infusion or stop the infusion depending on severity and provide appropriate medical treatment as necessary. If patient condition is stable, resume at a lower infusion rate. If Grade 2 or higher Infusion-Related Reaction occurs, administer premedications for subsequent infusions. If anaphylactic or life-threatening infusion reaction, BLENREP should be permanently discontinued and appropriate emergency care provided. Evaluation of patients with new or worsening unexplained pulmonary symptoms (e.g. cough, dyspnea) should be performed to exclude possible pneumonitis. In case of suspected Grade 3 or higher pneumonitis, BLENREP should be withheld. If Grade 3 or higher pneumonitis is confirmed, appropriate treatment should be initiated. BLENREP should only be resumed after an evaluation of the benefit and risk.
**Interactions:** There is a low risk of pharmacokinetic or pharmacodynamic drug interactions for belantamab mafodotin.
**Fertility, pregnancy and lactation:** *Fertility*: Belantamab mafodotin may impair fertility in females and males of reproductive potential. Women of childbearing potential who may desire children should be counselled prior to therapy regarding the option of having eggs frozen before treatment. Men are advised to have sperm samples frozen and stored before treatment. *Pregnancy*: BLENREP should not be used during pregnancy unless the benefit to the mother outweighs the potential risks to the foetus. *Lactation*: Women should be advised to discontinue breast-feeding prior to initiating treatment with BLENREP and for 3 months after the last dose.
**Effects on ability to drive and use machines:** BLENREP has a moderate influence on the ability to drive or use machines. Patients should be advised to use caution when driving or operating machines as BLENREP may affect their vision.
**Undesirable effects:** The most commonly reported adverse reactions were keratopathy and thrombocytopenia. The most commonly reported serious adverse reactions were pneumonia, pyrexia and infusion related reactions. Very common (≥1/10): Pneumonia, thrombocytopenia, anaemia, lymphopenia, leukopenia, neutropenia, keratopathy, blurred vision events, dry eye events, nausea, diarrhoea, pyrexia, fatigue, increased aspartate aminotransferase, increased gamma glutamyltransferase and infusion related reactions. Common (≥1/100 to <1/10) : Upper respiratory tract infection, photophobia, eye irritation, vomiting, increased creatine phosphokinase and albuminuria. Uncommon (≥1/1000 to <1/100) Ulcerative keratitis and Infective keratitis. Frequency not known: Corneal hypoesthesia and pneumonitis. Refer to the BLENREP Summary o f Product Characteristics for a full list of adverse events and the safety information.

**Overdose:** Refer to SmPC. **Legal Category:** POM.

**Pack size:** 1 x vial £5707.83

**MA Number:** PLGB 19494/0296

**MA Holder :** GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom. *Full SmPC available from GSK or from www.medicines.org.uk.*

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**PI Job Bag Numbers :** PI-7751 v5.0

**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**