PRESCRIBING INFORMATION (UK): BENLYSTA▼ (belimumab) 120mg and 400mg powder for concentrate for solution for infusion **Refer to Summary of Product Characteristics (SmPC) before prescribing**. Benlysta is a human IgG1λ monoclonal antibody specific for soluble human B Lymphocyte Stimulator protein. **Indication**: Add-on therapy in patients aged ≥5 years with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy. **Dosage & administration**: Treatment should be initiated and supervised by qualified physician experienced in diagnosis and treatment of SLE. Infusions should be administered by qualified healthcare professional trained to give infusion therapy. Severe or life-threatening hypersensitivity reactions and infusion reactions can occur, possibly after several hours and can recur after initial treatment of symptoms. Administer in an environment where resources for managing reactions are available. Clinical supervision required for several hours after infusion, following at least first 2 infusions. Make patients aware of potential risk of hypersensitivity reactions (day of, or several days after infusion, including signs/symptoms and recurrence) and provide package leaflet each time Benlysta administered. *Premedication:* An antihistamine, with/without an antipyretic, may be administered. *Dose*: 10 mg/kg intravenously by infusion over 1-hour on days 0, 14 and 28, and at 4-week intervals thereafter. Monitor patient continuously. Reconstitute and dilute before use (see SmPC for instructions); infuse over 1-hour (not bolus). Infusion rate may be slowed/interrupted if patient develops an infusion reaction. Discontinue if patient experiences potentially life-threatening adverse reaction. Consider discontinuation if no improvement after 6 months. *Elderly (≥65 years):* Use with caution. Dose adjustment not required. *Renal impairment:* Caution in severe impairment. *Paediatric population (≥5 years):* 10 mg/kg Benlysta on Days 0, 14 and 28, and at 4-week intervals thereafter; no data for <5 years. **Contraindications**: Hypersensitivity to belimumab or any excipients. **Warnings and precautions** (see SmPC for details): Record tradename and batch number. *Not recommended in:* severe active central nervous system lupus; severe active lupus nephritis; HIV; history of/current hepatitis B or C; hypogammaglobulinaemia (IgG <400 mg/dl) or IgA deficiency (IgA <10 mg/dl); history of major organ transplant or hematopoietic stem cell/marrow transplant or renal transplant. *Caution:* If Benlysta co-administered with other B cell targeted therapy or cyclophosphamide and patients with history of malignancy or who develop malignancy whilst receiving treatment. *Infusion reactions and hypersensitivity:* Administration may cause hypersensitivity or infusion reactions which can be severe and fatal. Interrupt administration and administer appropriate medical therapy. Delayed-type, non-acute hypersensitivity reactions (e.g. rash, nausea, fatigue, myalgia, headache, facial oedema) possible. *Infections*: Increased risk of infections - younger children may be at increased risk. Fatal infections (e.g. pneumonia and sepsis) occurred more frequently in patients receiving Benlysta; consider pneumococcal vaccination prior to initiation. Do not initiate with active serious infections (including serious chronic); Exercise caution and assess risk/benefit in patients with history of recurrent infection. Carefully monitor new infections - consider interrupting Benlysta. *Depression and suicidality*: Before treatment assess risk of depression and suicide in patient; closely monitor during treatment – consider discontinuation if new or worsening psychiatric symptoms. *Progressive multifocal leukoencephalopathy (PML):* Monitor for new or worsening signs/symptoms – refer to neurologist if suspected; suspend further dosing until excluded. *Immunisation*: Do not give live vaccines 30 days before, or concurrently with Benlysta. **Interactions**: No interaction studies. A risk for indirect reduction of CYP activity possible: on initiation or discontinuation of Benlysta, therapeutic monitoring should be considered for patients on CYP substrates with a narrow therapeutic index, where the dose is individually adjusted (e.g. warfarin). **Pregnancy and lactation**: Women of childbearing potential must use effective contraception during and at least 4 months after last treatment. Limited data on use in pregnant women. Benlysta should not be used during pregnancy unless potential benefit justifies potential risk to foetus. Not known if Benlysta is excreted in human milk or absorbed after ingestion. Maternal IgG is secreted in breast milk so recommended to either discontinue Benlysta or breast feeding depending on risk/benefit to mother and child. **Undesirable effects**: See SmPC for full list. *Very common (≥1/10):* Bacterial infections (e.g. bronchitis, urinary tract infection), diarrhoea, nausea. *Common (≥1/100 to <1/10):* Gastroenteritis viral, pharyngitis, nasopharyngitis, viral upper respiratory tract infection, leucopenia, hypersensitivity reactions, depression, migraine, pain in extremity, infusion-related systemic reactions, pyrexia. *Serious*: Anaphylactic reaction, suicidal ideation and behaviour. *Paediatric population:* no new safety signals in ≥12-year olds; limited data in <12 year olds, see SmPC for information on *infections*. **Basic NHS Costs**: Available as 120mg and 400mg vials containing white/off-white powder for reconstitution to provide 80mg/ml belimumab. 1 x 120mg vial, £121.50, 1 x 400mg vial, £405.00. **Legal category**: POM. **Marketing authorisation numbers**: 120mg EU/1/11/700/001; 400mg EU/1/11/700/002. **Marketing authorisation holder**: GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **Further information from**: *Freephone:* 0800 221 441. *Email:* customercontactuk@gsk.com.
PI-6225; Date of prep: July 2020.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard 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