**PRESCRIBING INFORMATION (UK)**: BENLYSTA▼ (belimumab) 200mg solution for injection in pre-filled pen. **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 adult patients 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. First subcutaneous (SC) injection should be supervised by a healthcare professional in a setting qualified to manage hypersensitivity reactions. Provide patient education on signs/symptoms of hypersensitivity reactions (day of, or several days after administration) and possibility of recurrence and training in SC technique. Inform patients to seek medical attention if symptoms experienced and provide package leaflet. Patient or caregiver may administer after HCP deems appropriate. *Dose*: 200 mg once weekly (not weight dependent). *Administration*: subcutaneous injection to abdomen or thigh, change site each week (see package leaflet for instructions). Monitor patient continuously. Consider discontinuation if no improvement after 6 months. *Missed dose:* If dose missed administer as soon as possible, then resume on usual day of administration or start new weekly schedule from day of missed dose administered. To change scheduled dosing day, new dose can be given on newly preferred day; Continue with the new weekly schedule from that day, even if dosing interval temporarily <1 week. *Transition from intravenous (IV) to SC*: first SC injection should be administered 1-4 weeks after last IV dose. *Elderly (≥65 years):* Use with caution. Dose adjustment not required. *Renal impairment:* Dose adjustment not required. Caution in severe impairment. *Paediatric population (<18 years):* no data. **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. *Hypersensitivity:* Administration may cause hypersensitivity reactions which can be severe and fatal. Interrupt administration and administer appropriate medical therapy. Risk is greatest with first two doses; risk should be considered for every injection. Advise patients reactions are possible on day of, or several days after. Delayed-type, non-acute hypersensitivity reactions (e.g. rash, nausea, fatigue, myalgia, headache, facial oedema) possible. *Infections*: Increased risk of infections, including opportunistic. 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 immunosuppressants including Benlysta until infection resolved. *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. *Malignancy*: May be increased risk with immunomodulatory medicines including 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 systemically 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, injection site reactions, pain in extremity, injection-related systemic reactions, pyrexia. *Serious*: Anaphylactic reaction, suicidal ideation and behaviour. **Basic NHS Costs**: Temporary supply during COVID-19 pandemic; list price unavailable. **Legal category**: POM. **Marketing authorisation numbers**: EU/1/11/700/003 (1 pre-filled pen); EU/1/11/700/004 (4 pre-filled pens). **Marketing authorisation holder**: GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **Further information**: *Freephone:* 0800 221 441. *Email:* customercontactuk@gsk.com.
PI-5737; Date of prep: September 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