

## Benlysta (belimumab) - Updated dosing

- On June 24, 2025, <u>GSK announced</u> the <u>FDA approval</u> of the <u>subcutaneous</u> (SC) autoinjector formulation of <u>Benlysta</u> (<u>belimumab</u>), for the treatment of patients 5 years of age and older with active lupus nephritis (LN) who are receiving standard therapy.
  - Previously, only the intravenous (IV) formulation of Benlysta was approved for LN in pediatric patients.
- Both SC and IV administration of Benlysta are also approved for the treatment of patients 5 years
  of age and older with active systemic lupus erythematosus (SLE) who are receiving standard
  therapy.
- In pediatric patients 5 years of age and older with LN, the SC dose of Benlysta via the autoinjector is as follows:
  - Patients greater than or equal to 40 kg: 400 mg once weekly for 4 doses, followed by 200 mg once weekly
  - Patients 15 kg to less than 40 kg: 200 mg once weekly for 4 doses, followed by 200 mg once every 2 weeks.
- The first SC injection of Benlysta should be administered under the supervision of a healthcare
  provider. Patients or caregivers should be provided with proper training on SC administration and
  education about signs and symptoms of hypersensitivity reactions.
  - For adults and pediatric patients 10 years of age and older, subsequent SC Benlysta administrations may be performed by the patient or trained caregiver, if determined to be appropriate. For pediatric patients less than 10 years of age, subsequent SC Benlysta administrations must be performed by a healthcare provider or trained caregiver.
- Refer to the Benlysta drug label for complete dosing and administration recommendations.



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