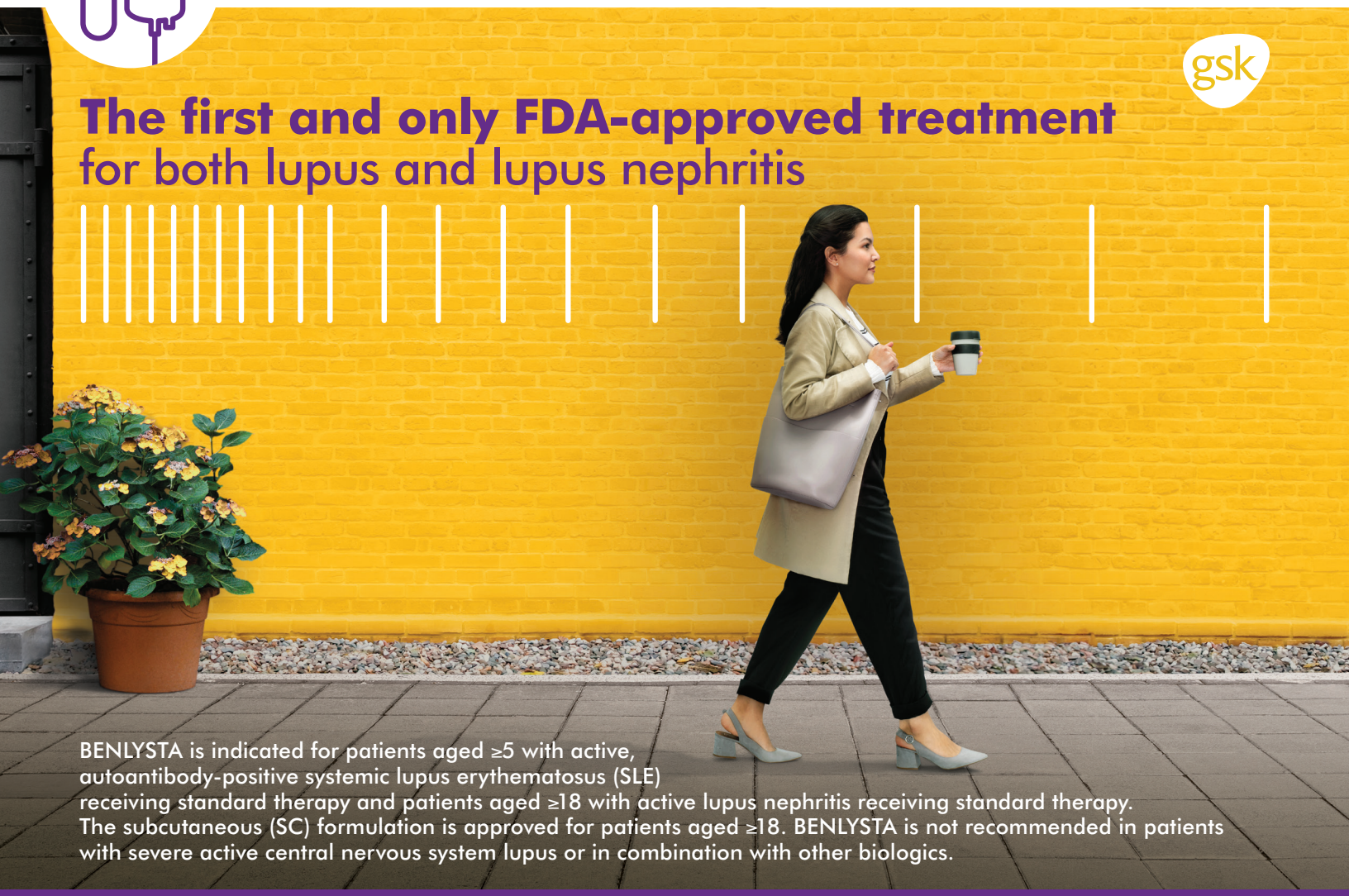
BENLYSTA GIVES YOUR PATIENTS WITH LUPUS NEPHRITIS THE CHOICE OF ADMINISTRATION OPTIONS

The first and only FDA-approved treatment for both lupus and lupus nephritis



BENLYSTA is indicated for patients aged ≥5 with active, autoantibody-positive systemic lupus erythematosus (SLE) receiving standard therapy and patients aged ≥18 with active lupus nephritis receiving standard therapy. The subcutaneous (SC) formulation is approved for patients aged ≥18. BENLYSTA is not recommended in patients with severe active central nervous system lupus or in combination with other biologics.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

Previous anaphylaxis with BENLYSTA.

WARNINGS AND PRECAUTIONS

Serious Infections: Serious and sometimes fatal infections have been reported in patients receiving immunosuppressive agents, including BENLYSTA. The incidence of serious infections was similar in patients receiving BENLYSTA versus placebo, whereas fatal infections occurred more frequently with BENLYSTA. The most frequent serious infections in adults treated with BENLYSTA IV included pneumonia, urinary tract infection, cellulitis, and bronchitis. Use caution in patients with severe or chronic infections, and consider interrupting therapy in patients with a new infection.

Progressive Multifocal Leukoencephalopathy (PML): Cases of JC virus-associated PML resulting in neurological deficits, including fatal cases, have been reported in patients with SLE receiving immunosuppressants, including BENLYSTA. If PML is confirmed, consider stopping immunosuppressant therapy, including BENLYSTA.

Hypersensitivity Reactions (Including Anaphylaxis): Acute hypersensitivity reactions, including anaphylaxis (eg, hypotension, angioedema, urticaria or other rash, pruritus, and dyspnea) and death, have been reported, including in patients who have previously tolerated BENLYSTA. Generally, reactions occurred within hours of the infusion but may occur later. Non-acute hypersensitivity reactions (eg, rash, nausea, fatigue, myalgia, headache, and facial edema) typically occurred up to a week after infusion. Patients with a history of multiple drug allergies or significant hypersensitivity may be at increased risk. With BENLYSTA SC, systemic hypersensitivity reactions were similar to those in IV trials.

Healthcare providers (HCPs) should monitor patients during and after IV administration and be prepared to manage anaphylaxis; discontinue immediately in the event of a serious reaction. Premedication may mitigate or mask a hypersensitivity response. Advise patients about hypersensitivity symptoms and instruct them to seek immediate medical care if a reaction occurs.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Medication Guide, for BENLYSTA.

Benlysta (belimumab)
Intravenous Use 120 mg/vial
Subcutaneous Use 200 mg/mL

ONCE-WEEKLY AUTOINJECTOR WITH AT-HOME CONVENIENCE

For adult patients with active lupus nephritis

Start

2 x 200 mg

for the first 4 doses, once per week,* for 4 weeks

Stay

200 mg

once per week

76% of patients with SLE taking BENLYSTA preferred administration with the autoinjector over IV infusion[1,2†]

99% of patients with SLE successfully administered BENLYSTA via autoinjector[3‡]

BENLYSTA for SC use is available as a 1-mL single-dose prefilled autoinjector

* The 400-mg dose requires administration of 2 autoinjectors (2 x 200 mg). The dose is given via subcutaneous injection in the abdomen or thigh. When the 400-mg dose is administered at the same site, it is recommended that the 2 individual 200-mg injections be administered at least 5 cm (approximately 2 inches) apart.

† A follow-up survey was conducted in patients (N=43) who completed an open-label, multi-dose, usability, tolerability, and safety study of subcutaneous (SC) belimumab in which patients with SLE were switched from belimumab administered via IV or pre-filled syringe to self-administered doses using the autoinjector for 8 weekly doses. Patients (n=42) were asked, "What is your preference for receiving BENLYSTA: using the autoinjector or IV?"[2]

‡ Open-label study assessed the correct use of the BENLYSTA Autoinjector in adult SLE patients (N=95). BENLYSTA was administered as a 200-mg subcutaneous injection by the patient for 8 weekly doses after being trained on proper use with the Autoinjector at Screening and Day 0. Successful use was determined by investigator observation and/or their review of the patient diary based on the Instructions for Use. Primary endpoint was to evaluate successful administration of observed first and second doses (Weeks 1 & 2;n/N=89/90).[3]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Infusion Reactions: Serious infusion reactions (eg, bradycardia, myalgia, headache, rash, urticaria, and hypotension) were reported in adults. HCPs should monitor patients and manage reactions if they occur. Premedication may mitigate or mask a reaction. If an infusion reaction develops, slow or interrupt the infusion.

Depression and Suicidality: In adult trials, psychiatric events reported more frequently with BENLYSTA IV related primarily to depression-related events, insomnia, and anxiety; serious psychiatric events included serious depression and suicidality, including 2 completed suicides. No serious depression-related events or suicides were reported in the BENLYSTA SC trial. Before adding BENLYSTA, assess patients' risk of depression and suicide and monitor them during treatment. Instruct patients/caregivers to contact their HCP if they experience new/worsening depression, suicidal thoughts, or other mood changes.

Malignancy: The impact of BENLYSTA on the development of malignancies is unknown; its mechanism of action could increase the risk for malignancies.

Immunization: Live vaccines should not be given for 30 days before or concurrently with BENLYSTA as clinical safety has not been established.

Use With Biologic Therapies: BENLYSTA has not been studied and is not recommended in combination with other biologic therapies, including B-cell targeted therapies.

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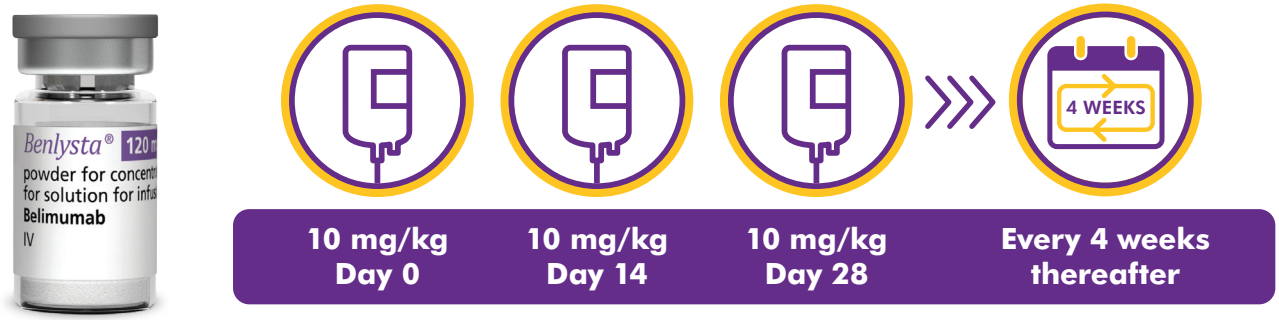
BENLYSTA IV DOSING FOR LUPUS NEPHRITIS

Scheduling the first 3 doses in advance may be helpful for patients

- 10 mg/kg at 2-week intervals for the first 3 doses and then once every 4 weeks thereafter

For patients **who prefer in-office infusions**



BENLYSTA for IV use is available as **120 mg in a 5-mL single-dose vial** and **400 mg in a 20-mL single-dose vial**.

For full instructions for SC and IV use, refer to the full Prescribing Information for BENLYSTA.

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common serious adverse reactions in adult SLE clinical trials were serious infections, BENLYSTA IV 6.0% (placebo 5.2%), some of which were fatal infections, BENLYSTA IV 0.3% (placebo 0.1%). Adverse reactions occurring in ≥3% of adults and ≥1% more than placebo: nausea 15% (12%); diarrhea 12% (9%); pyrexia 10% (8%); nasopharyngitis 9% (7%); bronchitis 9% (5%); insomnia 7% (5%); pain in extremity 6% (4%); depression 5% (4%); migraine 5% (4%); pharyngitis 5% (3%); cystitis 4% (3%); leukopenia 4% (2%); viral gastroenteritis 3% (1%).

In adult patients with active lupus nephritis, serious infections occurred in 14% of patients receiving BENLYSTA IV (placebo 17%), some of which were fatal infections, BENLYSTA 0.9% (placebo 0.9%). Adverse reactions occurring in ≥3% of adults and ≥1% more than placebo were consistent with the known safety profile of BENLYSTA IV in SLE patients.

Adverse reactions in pediatric patients aged ≥5 years receiving BENLYSTA IV were consistent with those observed in adults.

The safety profile observed for BENLYSTA SC in adults was consistent with the known safety profile of BENLYSTA IV with the exception of local injection site reactions.

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BENLYSTA AUTOINJECTOR – PREFERRED OVER IV INFUSION BY 3 OUT OF 4 PATIENTS WITH SLE[1,2]

A once-weekly dosing option with at-home convenience

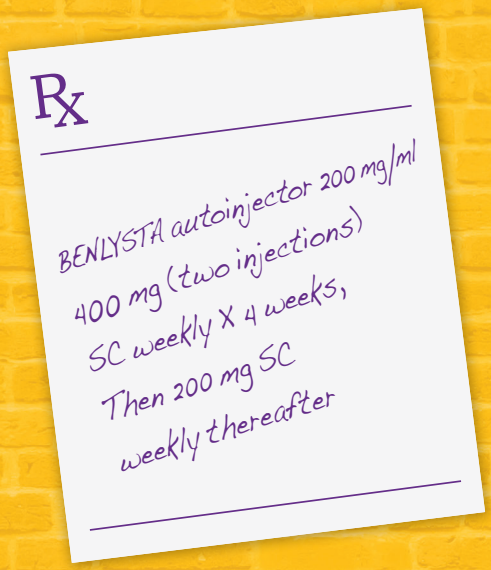
Start BENLYSTA for lupus nephritis

SC autoinjector

At-home once weekly dosing

IV Infusion

In-office infusion: 10 mg/kg at 2-week intervals for the first 3 doses and then once every 4 weeks thereafter



Learn more about BENLYSTA dosing at **BenlystaAutoinjector.com**

IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIFIC POPULATIONS

Pregnancy: There are insufficient data in pregnant women to establish whether there is drug-associated risk for major birth defects or miscarriage. After a risk/benefit assessment, if prevention is warranted, women of childbearing potential should use contraception during treatment and for ≥4 months after the final treatment.

Pregnancy Registry: HCPs are encouraged to register patients and pregnant women are encouraged to enroll themselves by calling 1-877-681-6296.

Lactation: No information is available on the presence of belimumab in human milk, the effects on the breastfed infant, or the effects on milk production. Consider developmental and health benefits of breastfeeding with the mother's clinical need for BENLYSTA and any potential adverse effects on the breastfed child or from the underlying maternal condition.

Pediatric Use: The safety and effectiveness have not been established for BENLYSTA IV in SLE patients <5 years of age, and in active LN patients <18 years of age, and for BENLYSTA SC in SLE and LN patients <18 years of age.

References: 1. Data on file, GSK. **2.** Dashiell-Aje E, Harding G, Pascoe K, *et al.* Patient evaluation of satisfaction and outcomes with an autoinjector for self-administration of subcutaneous belimumab in patients with systemic lupus erythematosus. *Patient.* 2018;11:119-129. **3.** Sheikh SZ, Hammer AE, Fox NL, *et al.* Evaluation of a novel autoinjector for subcutaneous self-administration of belimumab in systemic lupus erythematosus. *International Journal of Clinical Pharmacology and Therapeutics.* 2016;54:914-922.

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