

DETACH HERE AND GIVE MEDICATION GUIDE TO PATIENT.

<b>MEDICATION GUIDE</b>	
<b>BENLYSTA (ben-LIST-ah) (belimumab) for injection, for intravenous use</b>	<b>BENLYSTA (ben-LIST-ah) (belimumab) injection, for subcutaneous use</b>
<p><b>What is the most important information I should know about BENLYSTA?</b></p> <p>BENLYSTA can cause serious side effects. Some of these side effects may cause death. It is not known if BENLYSTA causes these serious side effects. Tell your healthcare provider right away if you have any of the symptoms listed below while receiving BENLYSTA</p>	
<p>1. <b>Infections.</b> Symptoms of an infection can include:</p> <ul style="list-style-type: none"><li>• fever</li><li>• chills</li><li>• pain or burning with urination</li><li>• urinating often</li><li>• coughing up mucus</li><li>• warm, red, or painful skin or sores on your body</li></ul>	
<p>2. <b>Heart Problems.</b> Symptoms of heart problems can include:</p> <ul style="list-style-type: none"><li>• chest discomfort or pain</li><li>• shortness of breath</li><li>• cold sweats</li><li>• nausea</li><li>• dizziness</li><li>• discomfort in other areas of the upper body</li></ul>	
<p>3. <b>Allergic (hypersensitivity) reactions.</b> Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death. Your healthcare provider will watch you closely while you are receiving BENLYSTA given intravenously (infusion) and after your infusion for signs of a reaction. Allergic reactions can sometimes be delayed. Tell your healthcare provider right away if you have any of the following symptoms of an allergic reaction following use of BENLYSTA:</p> <ul style="list-style-type: none"><li>• itching</li><li>• swelling of the face, lips, mouth, tongue, or throat</li><li>• trouble breathing</li><li>• anxiousness</li><li>• low blood pressure</li><li>• dizziness or fainting</li><li>• headache</li><li>• nausea</li><li>• skin rash</li></ul>	
<p>4. <b>Mental health problems and suicide.</b> Symptoms of mental health problems can include:</p> <ul style="list-style-type: none"><li>• thoughts of suicide or dying</li><li>• attempt to commit suicide</li><li>• trouble sleeping (insomnia)</li><li>• new or worse anxiety</li><li>• new or worse depression</li><li>• acting on dangerous impulses</li><li>• other unusual changes in your behavior or mood</li><li>• thoughts of hurting yourself or others</li></ul>	

**What is BENLYSTA?**

BENLYSTA is a prescription medicine used to treat patients with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines. Intravenous dosing of BENLYSTA is approved for adults and children aged 5 years and older. Subcutaneous dosing of BENLYSTA is only approved for adult patients.

BENLYSTA contains belimumab which is in a group of medicines called monoclonal antibodies. Lupus is a disease of the immune system (the body system that fights infection). When given together with other medicines for lupus, BENLYSTA decreases lupus disease activity more than other lupus medicines alone.

- It is not known if BENLYSTA is safe and effective in people with severe active lupus nephritis or severe active central nervous system lupus.

**Do not use BENLYSTA if you:**

- are allergic to belimumab or any of the ingredients in BENLYSTA. See the end of this Medication Guide for a complete list of ingredients in BENLYSTA.

**Before you receive BENLYSTA, tell your healthcare provider about all of your medical conditions, including if you:**

- think you have an infection or have infections that keep coming back. You should not receive BENLYSTA if you have an infection unless your healthcare provider tells you to. **See “What is the most important information I should know about BENLYSTA?”**
- have or have had mental health problems such as depression or thoughts of suicide.
- have recently received a vaccination or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not receive live vaccines.
- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies or IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. You should talk to your healthcare provider about whether to prevent pregnancy while on BENLYSTA. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving BENLYSTA and for at least 4 months after the final dose of BENLYSTA.
  - Tell your healthcare provider right away if you become pregnant during your treatment with BENLYSTA or if you think you may be pregnant.
- If you become pregnant while receiving BENLYSTA, talk to your healthcare provider about enrolling in the BENLYSTA Pregnancy Registry. You can enroll in this registry by calling 1-877-681-6296. The purpose of this registry is to monitor the health of you and your baby.
- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your healthcare provider should talk about whether or not you should receive BENLYSTA and breastfeed.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you to show to your healthcare provider

and pharmacist when you get a new medicine.

### **How will I receive BENLYSTA?**

#### **When administered intravenously (by vein)**

- You will be given BENLYSTA by a healthcare provider through a needle placed in a vein (IV infusion). It takes about 1 hour to give you the full dose of BENLYSTA.
- Your healthcare provider will tell you how often you should receive BENLYSTA.
- Your healthcare provider may give you medicines before you receive BENLYSTA to help reduce your chance of having a reaction. A healthcare provider will watch you closely while you are receiving BENLYSTA and after your infusion for signs of a reaction. A healthcare provider will review the signs and symptoms of possible allergic reactions that could happen after your infusion.

#### **When administered subcutaneously (under your skin)**

- Use BENLYSTA exactly as your healthcare provider tells you to.
- Read the **Instructions for Use** that comes with BENLYSTA for instructions about the right way to give your injections at home.
- BENLYSTA may be prescribed as a single-dose autoinjector or as a single-dose prefilled syringe.
- Before you use BENLYSTA, your healthcare provider will show you or your caregiver how to give the injections and review the signs and symptoms of possible allergic reactions.
- BENLYSTA is injected under your skin (subcutaneously) of your stomach (abdomen) or thigh.
- Use BENLYSTA 1 time a week on the same day each week.
- If you miss your dose of BENLYSTA on your planned day, inject a dose as soon as you remember. Then, inject your next dose at your regularly scheduled time or continue weekly dosing based on the new day injected. In case you are not sure when to inject BENLYSTA, call your healthcare provider. Do not use 2 doses on the same day to make up for a missed dose.

### **What are the possible side effects of BENLYSTA?**

**BENLYSTA can cause serious side effects, including:**

**See “What is the most important information I should know about BENLYSTA?”**

- **Progressive multifocal leukoencephalopathy (PML).** PML is a serious and life-threatening brain infection. Your chance of getting PML may be higher if you are treated with medicines that weaken your immune system, including BENLYSTA. PML can result in death or severe disability. If you notice any new or worsening medical problems such as those below, tell your healthcare provider right away:
  - memory loss
  - trouble thinking
  - dizziness or loss of balance
  - difficulty talking or walking
  - loss of vision
- **Cancer.** BENLYSTA may reduce the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers.

**The most common side effects of BENLYSTA include:**

- nausea
- diarrhea
- fever
- leg or arm pain
- depression
- headache (migraine)

- stuffy or runny nose and sore throat (nasopharyngitis)
- persistent cough (bronchitis)
- trouble sleeping (insomnia)
- pain, redness, itching, or swelling at the site of injection (when given subcutaneously)

These are not all the possible side effects of BENLYSTA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store BENLYSTA?**

- Store autoinjectors and prefilled syringes in the refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Keep BENLYSTA autoinjectors and prefilled syringes in the original package until time of use to protect from light.
- Do not shake. Keep away from heat and sunlight.
- Do not use and do not place back in the refrigerator if left out at room temperature for more than 12 hours.
- Safely throw away medicine that is out of date or no longer needed.

**Keep BENLYSTA and all medicines out of the reach of children.**

#### **General information about the safe and effective use of BENLYSTA.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BENLYSTA for a condition for which it was not prescribed. Do not give BENLYSTA to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about BENLYSTA. You can ask your healthcare provider or pharmacist for information about BENLYSTA that is written for healthcare professionals.

#### **What are the ingredients in BENLYSTA?**

**Active ingredient:** belimumab.

**Inactive ingredients (intravenous):** citric acid, polysorbate 80, sodium citrate, sucrose.

**Inactive Ingredients (subcutaneous):** L-arginine hydrochloride, L-histidine, L-histidine monohydrochloride, polysorbate 80, sodium chloride.

For more information, go to [www.BENLYSTA.com](http://www.BENLYSTA.com) or call 1-877-423-6597

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