MEDICATION GUIDE

BENLYSTA® (ben-LIST-ah)
(belimumab)
Injection for intravenous use

Read this Medication Guide before you start receiving BENLYSTA and before each treatment. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about BENLYSTA?

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.

1. **Infections.** Symptoms of an infection can include:

   - fever
   - chills
   - pain or burning with urination
   - urinating often
   - bloody diarrhea
   - coughing up mucus

2. **Heart Problems.** Symptoms of heart problems can include:

   - chest discomfort or pain
   - shortness of breath
   - cold sweats
   - nausea
   - dizziness
   - discomfort in other areas of the upper body

3. **Mental health problems and suicide.** Symptoms of mental health problems can include:

   - thoughts of suicide or dying
   - attempt to commit suicide
   - trouble sleeping (insomnia)
   - new or worse anxiety
   - new or worse depression
   - acting on dangerous impulses
   - other unusual changes in your behavior or mood
   - thoughts of hurting yourself or others

What is BENLYSTA?

BENLYSTA is a prescription medicine used to treat adults with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines.

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). People with active lupus often have high levels of a certain protein in their blood. BENLYSTA binds to and limits the activity of the protein. 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.

- It is not known if BENLYSTA is safe and effective in children.

Who should not receive BENLYSTA?

Do not receive 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.

What should I tell my healthcare provider before receiving BENLYSTA?

Before you receive BENLYSTA, tell your healthcare provider 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
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with BENLYSTA.
- 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 decide if you will receive BENLYSTA or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription 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?

- 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.

What are the possible side effects of BENLYSTA?

BENLYSTA can cause serious side effects.

- **See "What is the most important information I should know about BENLYSTA?"**

- **Cancer.** BENLYSTA may reduce the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers.

- **Allergic (hypersensitivity) and infusion reactions.** Serious allergic or infusion reactions can happen on the day of or days after receiving BENLYSTA and may cause death. Your healthcare provider will watch you closely while you are receiving BENLYSTA 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 or infusion reaction:

  - itching
  - swelling of the face, lips, mouth, tongue, or throat

- trouble breathing
- anxiousness
- low blood pressure
- dizziness or fainting
- headache
- nausea
- skin rash, redness, or swelling

- **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

The most common side effects of BENLYSTA include:

- nausea
- diarrhea
- fever
- stuffy or runny nose
- sore throat
- cough (bronchitis)
- trouble sleeping
- leg or arm pain
- depression
- headache (migraine)
- urinary tract infection
- decreased white blood cell count (leukopenia)
- vomiting
- stomach pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BENLYSTA. For more information, ask your healthcare provider.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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.

This Medication Guide summarizes the most important information about BENLYSTA. For more information about BENLYSTA, talk with your healthcare provider.

You can ask your healthcare provider or pharmacist for information about BENLYSTA that is written for healthcare professionals.

For more information about BENLYSTA, go to www.BENLYSTA.com or call 1-877-423-6597.

What are the ingredients in BENLYSTA?

Active ingredient: belimumab.
Inactive ingredients: citric acid, polysorbate 80, sodium citrate, sucrose.

BENLYSTA is a registered trademark of the GSK group of companies.

Manufactured by
GlaxoSmithKline Manufacturing SpA
43056 S. Polo di Torrile (PR), Italy

Manufactured for
Human Genome Sciences, Inc.
(a subsidiary of GlaxoSmithKline)
Rockville, Maryland 20850
US License No. 1820

Marketed by

GlaxoSmithKline
Research Triangle Park NC 27709

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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