

Before receiving BENLYSTA



What is BENLYSTA?

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

It is not known if BENLYSTA is safe and effective in people with severe active lupus nephritis or severe active central nervous system lupus, and it has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of BENLYSTA is not recommended in these situations.

Talk with your healthcare provider

Before receiving BENLYSTA also discuss with 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.
- 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 taking other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies or intravenous 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. If you are able to become pregnant, you should talk to your healthcare provider about whether or not to use birth control (contraception) and receive BENLYSTA. If BENLYSTA is recommended, 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 or you think you may be pregnant while receiving treatment with BENLYSTA. If you become pregnant, 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 the 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 discuss whether or not you should receive BENLYSTA and breastfeed.

Available resources to consider

Ask your healthcare professional about your insurance benefits and financial assistance options. It's important to have a clear understanding of your insurance coverage for BENLYSTA. If you have additional questions regarding your insurance coverage or financial assistance, feel free to call the BENLYSTA® Gateway at 1-877-4-BENLYSTA (1-877-423-6597).

Sign the BENLYSTA Gateway enrollment form. Your healthcare professional may ask you to sign this form if he or she is using this optional service to verify your insurance benefits. If you need help paying for BENLYSTA, the form can also be used to apply for one of our assistance programs. You can find a copy of this form inside page 31 of the Patient Education Resource Guide. Your healthcare professional will complete the form along with you and fax it to the BENLYSTA Gateway at 1-877-850-9901.

Call us with questions. If you've talked to your doctor and still have questions about BENLYSTA, your insurance benefits, or our financial assistance programs, you can call the BENLYSTA Gateway and get answers from a live person. Call 1-877-4-BENLYSTA (1-877-423-6597) toll-free, Monday through Friday, 8 AM to 8 PM Eastern Time.

Join BENLYSTA® Connects. You have the option to join this free, customized support program. Fill out a simple questionnaire to receive informative e-mails, a newsletter about BENLYSTA, and a personalized *Doctor Discussion Guide* for use in conversations with your doctor. Join by going to www.BENLYSTA.com, by using the reply card in the Patient Education Resource Guide, or by calling BENLYSTA Gateway at 1-877-4-BENLYSTA.

Make your first infusion appointment for BENLYSTA. Discuss with your healthcare provider where and when you will receive your first infusion of BENLYSTA. Write down your appointment details here.

Appointment time & date: _____

Location: _____

Phone number: _____

The day before your infusion of BENLYSTA...

Confirm your infusion appointment. Whether you'll be receiving your infusion at your doctor's office, an infusion center, or a hospital, give them a call the day before to confirm your appointment.

Confirm your transportation. If you've arranged for a ride to or from your appointment, follow up to confirm your ride's availability.

On the day of your infusion of BENLYSTA...

Bring something to do. It takes about one hour to receive the full dose of BENLYSTA. There is also preparation time before as well as observation time after the infusion that may vary, so consider bringing something to help you pass the time, such as:

- A book
- A music player & headphones
- A portable video player
- A friend or family member to talk to
- Magazines
- A crossword puzzle
- A small pillow

When you arrive for your infusion, tell the attending healthcare provider if you have any allergies. You may receive medication prior to the infusion, which may help reduce your chance of having an allergic reaction. It is not known if these medications will help reduce the chance of an allergic reaction to BENLYSTA. A healthcare provider will watch you closely while you are receiving BENLYSTA and after your infusion for signs of a reaction.

Please see additional Important Safety Information on reverse side. Please see full Prescribing Information and Medication Guide for BENLYSTA, available at www.BENLYSTA.com

Things to watch for...

Serious allergic or infusion reactions can happen on the day of or days after receiving BENLYSTA and may cause death. Symptoms of an allergic or infusion reaction may include:

- 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

Your healthcare provider will watch you closely while you are receiving BENLYSTA and after your infusion for signs of a reaction. Tell your healthcare provider or get emergency medical help right away if you have any of these symptoms.

After your infusion of BENLYSTA® (belimumab)...

Depending on how you feel, you may be able to return to your usual activities. **Tell your healthcare provider** if you have any side effect that bothers you or that does not go away.

Going forward...

If you have any questions, call your doctor or BENLYSTA® Gateway at **1-877-4-BENLYSTA (1-877-423-6597), Monday through Friday, 8 AM to 8 PM Eastern Time.**

Do not receive BENLYSTA if you are allergic to belimumab or to any of the ingredients in BENLYSTA.

Important Safety Information

The most important information to 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

- **Infections:** Symptoms can include fever, chills, pain or burning with urination, urinating often, coughing up mucus, or skin or sores that are warm, red or painful.
- **Heart problems:** Symptoms can include chest discomfort or pain, shortness of breath, cold sweats, nausea, dizziness, or discomfort in other areas of the upper body.
- **Mental health problems and suicide:** Symptoms can include thoughts of suicide or dying, attempt to commit suicide, trouble sleeping (insomnia), new or worse anxiety or depression, acting on dangerous impulses, other unusual changes in your behavior or mood, or thoughts of hurting yourself or others.

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- 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 taking other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies or intravenous 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. If you are able to become pregnant, you should talk to your healthcare provider about whether or not to use birth control (contraception) and receive BENLYSTA. If BENLYSTA is recommended, 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 or you think you may be pregnant while receiving treatment with BENLYSTA. If you become pregnant, 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 the 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 discuss whether or not you should receive BENLYSTA and breastfeed.

Possible side effects of 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 a reaction: itching; swelling of the face, lips, mouth, tongue, or throat; trouble breathing; anxiousness; low blood pressure; dizziness or fainting; headache; nausea; or skin rash, redness, or swelling. Tell your healthcare provider or get emergency medical help right away if you have any of these symptoms.
- **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 the following, tell your healthcare provider right away: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, or loss of vision.

The most common side effects of BENLYSTA include:

- Nausea
- Diarrhea
- Fever
- Stuffy or runny nose and sore throat (nasopharyngitis)
- Cough (bronchitis)
- Trouble sleeping
- Leg or arm pain
- Depression
- Diarrhea
- Headache (migraine)

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.

Other Important Information

In 2 of 3 studies, fewer blacks/African Americans who received BENLYSTA responded to treatment compared to blacks/African Americans who did not receive BENLYSTA. Therefore, it is important to discuss with your healthcare provider whether BENLYSTA is right for you. A clinical trial is ongoing to study BENLYSTA specifically in blacks/African Americans with lupus.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information, visit www.BENLYSTA.com. Call BENLYSTA® Gateway at **1-877-4-BENLYSTA (1-877-423-6597) Monday through Friday, 8 AM to 8 PM Eastern Time.**

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