

Doctor Discussion Guide



If you are considering BENLYSTA, the following Doctor Discussion Guide might help you and your doctor decide if this medicine may be right for you.

To help you get started...

- At your doctor's appointment, tell your doctor that you have a few questions about BENLYSTA
- Be sure to take notes in the space provided below
- Don't hesitate to ask your doctor to repeat a response or speak slower so you can get all the answers you need

What is BENLYSTA?

BENLYSTA is a prescription medication 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.

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.

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

Important Safety Information

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 symptoms of infections (such as fever, chills, coughing up mucus, pain or burning with urination, urinating often, or warm, red, or painful skin or sores on your body), heart problems (such as chest discomfort or pain, or shortness of breath), allergic reactions (itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, or skin rash) or mental health problems (such as thoughts of suicide or dying, trouble sleeping (insomnia), new or worse anxiety or depression, acting on dangerous impulses). Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death.

Considering BENLYSTA?

Here are some questions to discuss with your doctor to see if BENLYSTA might be right for you.

1. My lupus is still active even though I am taking my lupus medications regularly.

Is there anything more we can do?

2. I am currently on the following medication(s): _____. What are the potential benefits of adding BENLYSTA?

3. How long does it take for BENLYSTA to work? How long would I take BENLYSTA?

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

TODAY'S THE DAY

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4. Can you tell me about your other patients' experience with BENLYSTA?

5. How will I know if BENLYSTA is reducing my disease activity?

6. What are the possible side effects of BENLYSTA?

7. How is BENLYSTA administered? Which option would be best for me?

8. What are my payments for BENLYSTA? Is there any financial support available?

9. Who should I contact if I have more questions about BENLYSTA?

Important Safety Information (cont'd)

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.
- 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 IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- have any other medical conditions.



TODAY'S THE DAY

Important Safety Information

Important Safety Information (cont'd)

Tell your healthcare provider if you (cont'd):

- 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.
- 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.

Possible side effects of BENLYSTA

Progressive multifocal leukoencephalopathy (PML) is a serious and life-threatening brain infection. PML can result in death or severe disability. Tell your healthcare provider right away if you notice any new or worsening medical problems: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, or loss of vision.

Medicines that affect the immune system, including BENLYSTA, may increase your risk of certain cancers.

The most common side effects of BENLYSTA are nausea, diarrhea, fever, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and 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.

Other Important Information

In clinical studies, there have been mixed results regarding how well BENLYSTA works in black/African American patients. Therefore, you should consult with your healthcare provider to determine if BENLYSTA is right for you.

For more information about BENLYSTA, visit www.Benlysta.com or call 1-877-4-BENLYSTA (1-877-423-6597).

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.

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

TODAY'S THE DAY



IMPORTANT FACTS ABOUT BENLYSTA

The risk information presented here is not comprehensive. To learn more, talk to your healthcare provider (HCP). Visit www.BENLYSTA.com or call 1-877-423-6597 to get FDA-approved product labeling, including Medication Guide.

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 HCP right away if you get any of the following signs or symptoms while receiving BENLYSTA:

- **Infections.** Symptoms can include: fever, chills, pain or burning with urination, urinating often, coughing up mucus, warm, red, or painful skin or sores on your body.
- **Heart problems.** Symptoms can include: chest discomfort or pain, shortness of breath, cold sweats, nausea, dizziness, discomfort in other areas of the upper body.
- **Allergic (hypersensitivity) reactions.** Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death. Symptoms can include: itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, skin rash.
- **Mental health problems and suicide.** Symptoms can include: thoughts of suicide or dying, attempt to commit suicide, trouble sleeping, 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?

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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.

Who should not use BENLYSTA?

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

What should I tell my HCP before receiving BENLYSTA?

Before you receive BENLYSTA, tell your HCP about all 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 HCP 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.

- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your HCP should talk about whether or not you should receive BENLYSTA and breastfeed.

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

What are the possible side effects of BENLYSTA?

BENLYSTA can cause serious side effects including:

- **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. Tell your HCP right away if you notice any new or worsening medical problems such as: 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, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and pain, redness, itching, or swelling at the site of injection.

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.

Keep BENLYSTA and all medicines out of reach of children.

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