

Lupus flares making little things feel like a big deal?

BENLYSTA reduces disease activity and prevents flares.*

Results may vary.

*In clinical studies, when added to common lupus medications, BENLYSTA reduced disease activity and reduced severe lupus flares when compared to those medications alone.

BENLYSTA is a prescription medicine used to treat people 5 years of age and older with active systemic lupus erythematosus (SLE or lupus) or active lupus nephritis (LN) (lupus-related kidney inflammation) who are receiving other lupus medicines. It is not known if BENLYSTA is safe/effective in people with severe active central nervous system lupus.

It is not known if BENLYSTA, given under the skin, is safe/effective in:

- children with SLE under 5 years of age or weighing less than 33 lbs
- children with LN under 18 years of age

It is not known if BENLYSTA, given in a vein (intravenously), is safe and effective in children less than 5 years of age.

Important Safety Information

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

The most important information about BENLYSTA

Immunosuppressive agents, including BENLYSTA, can cause serious side effects. Some of these may cause death.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

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

Lupus flares

can have serious and lasting consequences.



Plus, lupus flares can lead to inflammation and organ damage.

Our immune system normally helps protect us from infection and disease. But in people with lupus, the immune system attacks the body. These attacks can cause inflammation, which can lead to the symptoms people with lupus experience during flares. And inflammation from lupus flares can cause long-term damage in many parts of the body.

Just one flare may cause permanent damage to a vital organ.

Approximately 40% of people with lupus will go on to develop lupus nephritis, where lupus causes inflammation and damage to the kidneys. A single lupus nephritis flare could shorten a kidney's lifespan by decades.

Important Safety Information (cont'd)

The most important information about BENLYSTA (cont'd)

- **Infections:** fever, chills, pain or burning with urination, urinating often, coughing up mucus, or warm, red, or painful skin or sores on your body. Infections could be serious, leading to hospitalization or death.

- **Allergic (hypersensitivity) 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. Serious allergic reactions can happen the day of, or in days after, receiving BENLYSTA and may cause death.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Benlysta
(belimumab) 



Active lupus can cause symptoms to return or worsen.

BENLYSTA is proven to reduce disease activity.*

Results may vary.

*In clinical studies, when added to common lupus medications, BENLYSTA reduced disease activity when compared to those medications alone.

Important Safety Information (cont'd)

The most important information about BENLYSTA (cont'd)

- **Mental health problems and suicide:** 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.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Do your lupus flares make little things feel like a big deal?

BENLYSTA prevents lupus flares.[†]

Adding BENLYSTA to lupus treatments can mean:



Less symptoms[‡]

Lupus symptom improvements were mainly seen in the muscles, joints, skin, mouth, and the immune system.



Less steroids[‡]

BENLYSTA reduced steroid dose by 25% or more (to a daily dose of 7.5 mg or less) during Weeks 40-52, in patients receiving 7.5 mg or higher daily doses of steroid at the start of the studies.[§]



Less flares[‡]

In clinical trials, people adding BENLYSTA to their treatment plan decreased their risk of severe flares in the first year of use.

Results may vary.

[†]BENLYSTA reduced severe lupus flares. [‡]Compared to other lupus medications alone. [§]A reduction of steroid dose was seen but was not statistically significant.

If you're still having flares, even on medications for lupus, it's time to ask about BENLYSTA.

Before receiving BENLYSTA, discuss with your healthcare provider if you:

- think you have an infection or have infections that keep coming back. Do not use BENLYSTA if you have an infection unless your healthcare provider tells you to.

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Nearly 4 out of 10 people with lupus will develop kidney disease.

Lupus nephritis is a serious complication of lupus, and symptoms are often not apparent in early stages. **Be proactive by staying up to date on blood and urine tests**, and make sure to **tell your doctor if you are having any new or worsening symptoms**. It could be a sign that your lupus is active and possibly affecting your kidneys.



Adding BENLYSTA to lupus nephritis treatments can mean:



Less kidney disease activity*

BENLYSTA helped maintain kidney function and reduce protein in the urine.



Less steroids*

BENLYSTA helped reduce the need for rescue medicines such as high-dose steroids (greater than 10 mg/day).



Less kidney worsening*

BENLYSTA helped maintain kidney function and protect from further kidney worsening.



BENLYSTA could protect your kidneys.[†]

Results may vary.

*Compared to other lupus medicines alone. [†]In a lupus nephritis trial, BENLYSTA reduced kidney disease activity and showed kidney protection by reducing worsening.

Important Safety Information (cont'd)

Before receiving BENLYSTA, discuss with your healthcare provider if you: (cont'd)

- have or have had mental health problems such as depression or thoughts of suicide.
 - have recently received or may need a vaccination.
- If you are receiving BENLYSTA, you should not receive live vaccines.

- are taking any medicines, including prescription, over-the-counter, vitamins, and herbal supplements.
- are allergic to other medicines.
- are receiving other biologic medicines.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Benlysta
(belimumab)



BENLYSTA:



Works differently than standard treatments for lupus.

BENLYSTA is a biologic therapy, not a steroid. It doesn't suppress your entire immune system.



Targets an underlying cause of lupus.

BENLYSTA affects an immune process that can lead to inflammation in people with lupus and lupus nephritis. Adding BENLYSTA to your current treatment plan may help reduce the abnormal immune system activity that can contribute to disease activity in lupus.

Important Safety Information (cont'd)

Before receiving BENLYSTA, discuss with your healthcare provider if you: (cont'd)

- have or have had any type of cancer.
- have any other medical conditions.

- are pregnant or plan to become pregnant. It is unknown if BENLYSTA will harm your unborn baby. 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 for at least 4 months after the final dose of BENLYSTA.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Benlysta
(belimumab) 

You take BENLYSTA with your other lupus or lupus nephritis medicines.



BENLYSTA is prescribed alongside other lupus medications, including corticosteroids (such as prednisone), antimalarials (such as Plaquenil®), and immunosuppressive agents (such as CellCept® or methotrexate). In clinical trials, BENLYSTA was administered with other drugs, such as antihypertensives, ACE inhibitors, statins, and NSAIDs.

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Ask your doctor if adding BENLYSTA could help you reach your treatment goals.

BENLYSTA is the



FDA-approved biologic for both lupus and lupus nephritis

More than



since doctors began prescribing BENLYSTA

Important Safety Information (cont'd)

Before receiving BENLYSTA, discuss with your healthcare provider if you: (cont'd)

- 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 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/benlysta-belimumab/>.

- are breastfeeding or plan to breastfeed. It is unknown if BENLYSTA passes into your breast milk.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Benlysta
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Get the support you need, when you need it, with BENLYSTA Cares.

It's easy to find the resources you need to help manage your BENLYSTA treatment. BENLYSTA Cares is a patient support program designed for warriors just like you.

You could pay as little as \$0 for BENLYSTA*

The BENLYSTA Copay Program may help commercially insured patients with their out-of-pocket costs for BENLYSTA. Eligibility restrictions and program maximums apply. We can help you navigate your insurance coverage and determine if you're eligible for copay support and assistance.

*The maximum amount available per year from the copay program for most patients is \$9450. Patients in health plans that do not allow the amounts available from the copay program to count towards their copay, coinsurance, deductible or other out-of-pocket cost-sharing obligations, sometimes referred to as "maximizer plans," are subject to a yearly program maximum of \$5000. Visit www.GSKCopayPrograms.com for complete information about Program Eligibility, Terms and Conditions.

Important Safety Information (cont'd)

Possible side effects of BENLYSTA

- **Progressive multifocal leukoencephalopathy (PML).** 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.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.



Have your BENLYSTA questions answered by experienced nurses.*



Find help navigating insurance coverage and determine copay assistance eligibility.



Get access to self-care tips.



Hear the stories of other lupus warriors.

Coverage and co-pay questions?

Call BENLYSTA Cares at 1-877-4-BENLYSTA (1-877-423-6597) Monday to Friday, 8 AM to 8 PM ET.

*Nurses from BENLYSTA Cares do not give medical advice and will direct you to your healthcare provider for any disease-, treatment-, or referral-related questions.

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



With BENLYSTA, there are options.

At-home administration

BENLYSTA for subcutaneous (SC) use is a weekly self-injection that can be taken from home after being trained by a healthcare provider. BENLYSTA is available for at-home use as an autoinjector or a prefilled syringe.



IV infusion

If you prefer the convenience of receiving BENLYSTA intravenous (IV) infusions, you can do so with the comfort of having a healthcare provider monitor you during and immediately after the infusion.



Important Safety Information (cont'd)

Possible side effects of BENLYSTA (cont'd)

The most common side effects of BENLYSTA are nausea, diarrhea, fever, stuffy or runny nose and sore throat, persistent 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.

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.

Please see accompanying Important Facts About BENLYSTA.

Benlysta
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Still having flares, even on medication? There may be more you can do. Ask your rheumatologist about adding BENLYSTA.

Scan to learn more or visit
[AskAboutBENLYSTA.com](https://www.AskAboutBENLYSTA.com)



 **BenlystaCares**

Have questions or need assistance?
Call 1-877-4-BENLYSTA
(1-877-423-6597)

Personalized Support

Benefits & Savings

Exclusive Resources

Whether you need treatment support or financial assistance,
BENLYSTA Cares may be able to help.

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PMUS-BELBROC240003 July 2024
Produced in USA.

Benlysta
(belimumab)  

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 and Instructions for Use.

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

Immunosuppressive agents, including BENLYSTA, can cause serious side effects. Some of these side effects may cause death. Tell your HCP right away if you get any of the following signs or symptoms while receiving BENLYSTA:

- **Infections.** Infections could be serious, leading to hospitalization or death. 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.
- **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?

BENLYSTA is a prescription medicine used to treat people 5 years of age and older with active systemic lupus erythematosus (SLE or lupus) or active lupus nephritis (LN) (lupus-related kidney inflammation) who are receiving other lupus medicines. It is not known if BENLYSTA is safe/effective in people with severe active central nervous system lupus.

It is not known if BENLYSTA, given under the skin, is safe/effective in:

- children with SLE under 5 years of age or weighing less than 33 lbs
- children with LN under 18 years of age

It is not known if BENLYSTA, given in a vein (intravenously), is safe and effective in children less than 5 years of age.

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 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 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 or monoclonal antibodies.
- 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 HCP 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.

- 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 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/benlysta-belimumab/>.
- 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, persistent 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 the FDA at 1-800-FDA-1088.

Keep BENLYSTA and all medicines out of reach of children.

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