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2. Belimumab

Belimumab

Pronunciation: *be-lim-ue-mab*

Generic name: belimumab

Brand name: [Benlysta](#)

Dosage form: single-dose vial for intravenous infusion, prefilled syringe for subcutaneous use, prefilled autoinjector for subcutaneous use

Drug class: [Selective immunosuppressants](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Nov 8, 2024.

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What is belimumab?

Belimumab (brand name [Benlysta](#)) is used to treat active [systemic lupus erythematosus \(SLE\)](#) or active [lupus nephritis](#) (lupus-related kidney inflammation) in adults and children 5 years of age and older. Belimumab is given with other lupus medicines.

Belimumab's mechanism of action involves targeting and blocking a protein called B-lymphocyte stimulator (BLyS) that usually helps B cells survive and produce antibodies. In lupus, B cells are overactive and these produce harmful autoantibodies that attack healthy tissue. By blocking BLyS, belimumab reduces the survival of B cells, decreases the production of autoantibodies, and helps to control the overactive immune response, improving the symptoms such as [fatigue](#), and [reducing flares](#) associated with SLE and lupus nephritis. See [How does Benlysta work for lupus?](#) for more information.

Belimumab gained FDA approval on March 9, 2011 under the brand name Benlysta. There is no belimumab generic or biosimilar.

Belimumab uses

Belimumab (brand name Benlysta) is used to treat adults and children aged 5 years and older (weighing at least 15 kg) with

- active systemic lupus erythematosus (SLE) when used with standard therapy
- active lupus nephritis (lupus-related kidney inflammation) patients when used with standard therapy.

Belimumab should not be used in patients with severe active central nervous system lupus as its effectiveness has not been evaluated.

Subcutaneous (SC) belimumab is only approved for use in adults and children aged 5 years and older or heavier than 33 pounds (15 kg) with SLE, or adults aged 18 or older with active lupus nephritis.

- Children with active lupus nephritis aged 5 through 18 years will receive belimumab as an IV infusion given by their healthcare provider.

Belimumab side effects

The **most common side effects of belimumab** are:

- nausea
- diarrhea
- fever
- [sore throat](#), runny or stuffy nose (nasopharyngitis)
- persistent cough (bronchitis)
- bronchitis
- pain, itching, redness, or swelling where an injection was given under the skin
- pain in your arms or legs
- headache (migraine)
- depression
- sleep problems ([insomnia](#)).

[Hair loss](#) and [weight gain](#) have **not** been reported as common side effects of belimumab.

Serious side effects and warnings

Belimumab is an immunosuppressive agent and carries a risk of the following serious side effects, some of which may be fatal in some people.

Infections. Infections could be serious, leading to hospitalization or death. Tell your healthcare provider right away if you have any of the following symptoms of an infection:

- fever
- urinating often
- chills
- coughing up mucus
- pain or burning with urination
- 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 belimumab and may cause death. Your healthcare provider will watch you closely while you are receiving belimumab given in a vein (intravenous 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 belimumab:

- itching

- low blood pressure
- swelling of the face, lips, mouth, tongue, or throat
- dizziness or fainting
- headache
- trouble breathing
- nausea
- anxiousness
- skin rash.

See [Can Benlysta cause an allergic reaction?](#) for more information.

Mental health problems and suicide. Symptoms of mental health problems can occur. Tell your healthcare provider right away if you have any of the following symptoms:

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

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 belimumab. 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. Belimumab may reduce the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers.

Live vaccines should not be given concurrently with this medicine.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Belimumab side effects](#) (more detail)

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Belimumab cost

The cost of belimumab will depend on your insurance plan and if you qualify for [Benlysta Copay assistance](#). The

Benlysta Cares Support team can help determine if you are eligible for insurance coverage and the Benlysta Copay program. [Benlysta Gateway](#) is a centralized program that helps guide you through the access and reimbursement process and you will need to work with your healthcare provider to fill out the [Benlysta Gateway Enrollment form](#).

See [Benlysta Prices, Coupons, Copay Cards & Patient Assistance](#) for more information and the full cost of belimumab.

Before receiving

Do not receive a belimumab injection or infusion if you are allergic to the active ingredient belimumab, Benlysta, or any of the inactive ingredients in the injection or infusion..

To make sure belimumab injection or infusion is safe for you, tell your healthcare provider about all your medical conditions, including if you:

- think you have an infection or have infections that keep coming back. You should not receive Belimumab 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 Belimumab, you should not receive live vaccines, such as measles, mumps, or varicella
- are allergic to other medicines
- are receiving other [cyclophosphamide](#), biologic medicines, or other monoclonal antibody medicines
- have or have had any type of cancer
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

This medicine may increase your risk of certain cancers by changing the way your immune system works. Ask your doctor about your individual risk.

Some people have thoughts about suicide while using belimumab. Your doctor will need to check your progress at regular visits. Your family or other caregivers should also be alert to changes in your mood or symptoms.

Pregnancy

It is not known if belimumab injection or infusion will harm your unborn baby or affect its immune system. You should talk to your healthcare provider about whether to prevent pregnancy while on belimumab. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving belimumab and for at least 4 months after the final dose.

Tell your healthcare provider right away if you become pregnant during your treatment with belimumab or if you think you may be pregnant. If you become pregnant while receiving belimumab, 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 [MotherToBaby](#) to enrol. The purpose of this registry is to collect information about the health of you and your baby.

Breastfeeding

It may not be safe to breastfeed while using belimumab. Ask your doctor about any risks.

How is belimumab administered?

Belimumab may be administered into a vein by a healthcare provider (this is called an IV infusion) or given under the skin (this is called subcutaneously) either by self-administration or by a healthcare provider.

Belimumab by vein (intravenously)

You will be given your belimumab infusion 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 belimumab but you may need to go into the place you are getting your infusion from for a short time before to receive any premedication you may need, and stay for a short time after to monitor for any infusion-related reactions.
- Your healthcare provider will tell you how often you should receive belimumab, but it is usually given every 2 to 4 weeks.
- Your healthcare provider may give you medicines before you receive belimumab to help reduce your chance of having a reaction. A healthcare provider will watch you closely while you are receiving belimumab 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.

Belimumab given under the skin (subcutaneously)

Belimumab injection is injected under the skin (subcutaneously), usually 1 time weekly on the same day each week, or the same day every 2 weeks.

- Belimumab is injected under the skin (subcutaneously) of your stomach (abdomen) or thigh (see [Where do you inject Benlysta?](#) for more information).
- Your healthcare provider will tell you how often and how much of belimumab you should use.
- Use it exactly as your healthcare provider tells you to.
- Read the Instructions for Use that comes with [Benlysta Package Insert](#) for instructions about the right way to give your injections at home.

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.

Belimumab may be prescribed as a **single-dose autoinjector** or as a **single-dose prefilled syringe**.

- The single-dose autoinjector is for use in adults and children 5 to less than 18 years of age.
- The single-dose prefilled syringe is for use in adults 18 years of age and older.
- For children less than 10 years of age, belimumab must be given by a healthcare provider or a trained caregiver

Do not inject this medicine into skin that is bruised, tender, red, or hard.

- Prepare an injection only when you are ready to give it. Do not use if the medicine looks cloudy, has changed colors, or has particles in it. Call your pharmacist for new medicine.
- You may be given other medications to help prevent serious side effects or an allergic reaction. Keep using these

medicines for as long as your doctor has prescribed.

- Take the syringe or injection pen out of the refrigerator and let it reach room temperature for 30 minutes before injecting your dose. Do not use if the medicine has been left at room temperature longer than 12 hours. Do not put it back into the refrigerator. Call your pharmacist for new medicine.
- Each prefilled syringe or injection pen is for one use only. Throw it away after one use, even if there is still medicine left inside.
- Use belimumab on the same day every 2 to 4 weeks, as your healthcare provider tells you.
- Throw away used needles, syringes, or injection pens in a puncture-proof "sharps" container. Follow state or local laws about how to dispose of this container. Keep it out of the reach of children and pets.

Belimumab dosing

The dose of belimumab depends on who is receiving belimumab (adult or child) and how it is given (IV or SC).

Usual adult belimumab dose for SLE:

Belimumab IV administration: Belimumab 10 mg/kg IV over 1 hour at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.

Belimumab SC administration: Belimumab 200 mg SC once a week in the abdomen or thigh (preferably on the same day each week).

- If transitioning from IV to subcutaneous administration, administer the first subcutaneous dose 1 to 4 weeks after the last IV dose:

Usual adult belimumab dose for lupus nephritis

Belimumab IV administration: Belimumab 10 mg/kg IV over 1 hour at 2-week intervals for the first 3 doses and at 4-week intervals thereafter

Belimumab SC administration: Belimumab 400 mg (two 200-mg injections) once a week for 4 doses, then 200 mg once a week thereafter in the abdomen or thigh (preferably on the same day each week).

- A patient may transition from IV to subcutaneous administration any time after the patient completes the first 2 intravenous doses. If transitioning, administer the first subcutaneous dose of 200 mg 1 to 2 weeks after the last intravenous dose.

Usual child belimumab dose for SLE (5 years and older):

Belimumab IV administration: Belimumab 10 mg/kg IV over 1 hour at 2-week intervals for the first 3 doses and at 4-week intervals thereafter

Belimumab SC administration:

- Patients ≥ 40 kg: Belimumab 200 mg once weekly
- Patients 15 kg to <40 kg: Belimumab 200 mg once every 2 weeks

For children less than 10 years of age, belimumab must be given by a healthcare provider or a trained caregiver.

Usual child belimumab dose for lupus nephritis (5 years and older)

Belimumab IV administration: Belimumab 10 mg/kg IV over 1 hour at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.

Belimumab SC administration: Belimumab SC has not been evaluated in this age group for this condition.

 [Detailed Belimumab dosage information](#)

Belimumab J Code

Belimumab J code is J0490 (Injection, Benlysta, 10 mg)

Belimumab is available as:

Intravenous Infusion:

- single-dose vial 120 mg or 400 mg of belimumab lyophilized powder for reconstitution and dilution before intravenous infusion.

Subcutaneous Injection:

- single-dose prefilled syringe 200 mg/mL of belimumab. The single-dose prefilled syringe is for use in adults aged 18 years of age and older.
- prefilled autoinjector 200 mg/mL of belimumab. The single-dose autoinjector is for use in adults and children aged 5 to less than 18 years of age.

What happens if I miss a dose?

If you miss your dose of belimumab on your planned day, inject a dose as soon as you remember. Then, inject your next dose at your regularly scheduled time or continue dosing based on the new day injected. Do not use 2 injections on the same day. In case you are not sure when to inject belimumab, call your healthcare provider.

Call your doctor for instructions if you miss an appointment for an intravenous infusion of belimumab.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Belimumab Prescribing Information

Review the [belimumab Prescribing Information](#) or [belimumab Package Insert](#) for more detailed information about this medicine. Discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

What should I avoid while using belimumab?

Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.

Do not receive a "live" vaccine while using belimumab. The vaccine may not work as well and may not fully protect you

from disease. Live vaccines include measles, mumps, rubella (MMR), rotavirus, typhoid, yellow fever, varicella (chickenpox), zoster ([shingles](#)), and nasal flu ([influenza](#)) vaccine.

What other drugs will affect belimumab?

Other drugs may interact with belimumab, including prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Tell your doctor about all your current medicines and any medicine you start or stop using.

Research does not support using belimumab with other biologic treatments, such as rituximab, in people with SLE because of the increased incidence of serious infections and post-injection systemic reactions.

 [Belimumab drug interactions](#) (more detail)

Does belimumab interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

belimumab

+

Enter a drug name

Add

Storage

Belimumab vials for intravenous infusion

Store belimumab vials for IV infusion in a refrigerator at 36F to 46F (2C to 8C). Store vials in the original carton until use to protect from light. Do not freeze. Avoid exposure to heat.

Belimumab autoinjectors and prefilled syringes for subcutaneous injection

Prior to dispensing and following dispensing. Refrigerate prefilled belimumab autoinjectors and prefilled syringes at 36F to 46F (2C to 8C). Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. Avoid exposure to heat.

Belimumab ingredients

Belimumab is only available as the brand name Benlysta.

Active ingredient: belimumab.

Benlysta 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.

Who makes belimumab?

GlaxoSmithKline LLC manufactures belimumab under the brand name Benlysta.

Belimumab Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for belimumab.

Benlysta (belimumab) - GlaxoSmithKline LLC



Formulation type	Strength
Autoinjector	200 mg/mL
Pre-Filled Syringe	200 mg/mL
Single-Dose Vial	120 mg
Single-Dose Vial	400 mg

View [Benlysta](#) information in detail.

Popular FAQ

What is the difference between Benlysta and Saphnelo?



How does Benlysta work for lupus?



References

- [Benlysta \(belimumab\) Prescribing Information](#)
- [Benlysta \(belimumab\) Package Insert](#)

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

DRUG STATUS

Availability

Rx Prescription only


[Pregnancy & Lactation](#)

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

 Drug history at FDA



User Reviews & Ratings

7.8 / 10

[66 Reviews](#)

Images

Benlysta (belimumab) 120 mg lyophilized powder for injection



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