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(For additional information [see "Belimumab: Drug information"](#) and [see "Belimumab: Pediatric drug information"](#))

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Benlysta

Brand Names: Canada

Benlysta

What is this drug used for?

- It is used to treat lupus.
- It is used to treat kidney problems caused by lupus.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have an infection.
- If you have nervous system problems caused by lupus.
- If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure

that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- You may have more of a chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu. Some infections have been very bad and even deadly.
- Make sure you are up to date with all your vaccines before treatment with this drug.
- Talk with your doctor if you have recently had a vaccine or before getting any vaccines. Vaccine use with this drug may either raise the chance of an infection or make the vaccine not work as well.
- This drug may lower how well the immune system works. Drugs that do this may raise the risk of certain types of cancer. If you have questions, talk with the doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- If you may become pregnant, you must use birth control while taking this drug and for some time after the last dose. Ask your doctor how long to use birth control. If you get pregnant, call your doctor right away.
- If you used this drug when you were pregnant, tell your baby's doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

Vials:

- Infusion reactions have happened with this drug. These have happened on the same day as the infusion. Tell your doctor if you have any bad effects during or

after the infusion.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Rarely, some allergic reactions have been deadly.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- New or worse behavior or mood changes like depression or thoughts of suicide.
- Chest pain or pressure.
- Slow heartbeat.
- Muscle pain.
- Dizziness or passing out.
- Shortness of breath.
- Cold sweats.
- Very upset stomach or throwing up.
- A very bad brain problem called progressive multifocal leukoencephalopathy (PML) has happened with this drug. It may cause disability or can be deadly. Tell your doctor right away if you have signs like confusion, memory problems, low mood (depression), change in the way you act, change in strength on 1 side is

greater than the other, trouble speaking or thinking, change in balance, or change in eyesight.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

All products:

- Trouble sleeping.
- Headache.
- Upset stomach.
- Diarrhea.
- Nose or throat irritation.
- Pain in arms or legs.

Auto-injector shot and prefilled syringes:

- Irritation where the shot is given.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

Auto-injector shot and prefilled syringes:

- It is given as a shot into the fatty part of the skin on the top of the thigh or the belly area.

- Take the same day each week.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- Before using this drug, take it out of the refrigerator and leave it at room temperature for 30 minutes.
- Do not heat or microwave.
- Do not shake.
- Move the site where you give the shot with each shot.
- Do not give into tender, bruised, red, or hard skin.
- Do not use if the solution is cloudy, leaking, or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Do not use this drug if it has been dropped or if it is broken.
- If your dose is more than 1 injection, you may give in the same body part. However, do not give injections within 2 inches of each other.
- Throw syringe away after use. Do not use the same syringe more than one time.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

Vials:

- It is given as an infusion into a vein over a period of time.
- Other drugs may be given before this drug to help avoid side effects.

What do I do if I miss a dose?

Auto-injector shot and prefilled syringes:

- Take a missed dose as soon as you think about it.

- After taking a missed dose, keep taking on your normal day or start a new weekly schedule based on the day the dose is taken.
- Do not take 2 doses on the same day.
- If you are not sure what to do if you miss a dose, call your doctor.

Vials:

- Call your doctor to find out what to do.

How do I store and/or throw out this drug?

Auto-injector shot and prefilled syringes:

- Store in a refrigerator. Do not freeze.
- Store in the original container to protect from light.
- If needed, this drug can be left out at room temperature for up to 12 hours before use. Throw away any part not used after 12 hours.
- Protect from heat and sunlight.
- Do not put this drug back in the refrigerator after it has been stored at room temperature.

Vials:

- If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

All products:

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine. The use of this information is governed by the Lexicomp End User License Agreement, available at <https://www.wolterskluwer.com/en/solutions/lexicomp/about/eula>.

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