



BENLYSTA AUTOINJECTOR

INSTRUCTIONS FOR USE



Please see accompanying full Prescribing Information, including Medication Guide, for BENLYSTA and Important Facts about BENLYSTA on pages 10-11.

Benlysta
(belimumab) 
Subcutaneous Use 200 mg/mL

BENLYSTA (BELIMUMAB) AUTOINJECTOR INSTRUCTIONS FOR USE

Read these instructions for use before you start to use BENLYSTA and each time you refill your prescription. You should also receive training from your healthcare provider on how to use the Autoinjector the right way. If you do not follow these instructions, the Autoinjector may not work properly. BENLYSTA is for use **under the skin only** (subcutaneous).

Important Storage Information

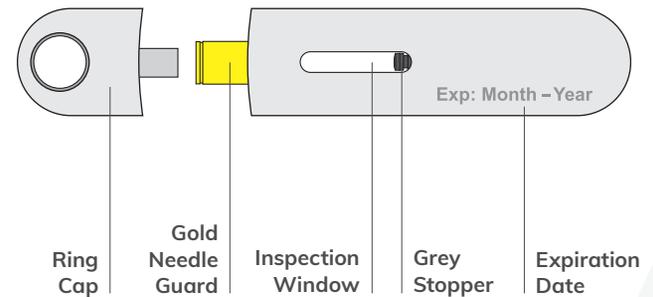
- Keep refrigerated until 30 minutes before use.
- Keep in the original package until time of use to protect from light.
- **Do not** freeze BENLYSTA.
- **Keep away from heat and sunlight.**
- **Do not** use and **do not** place back in the refrigerator if BENLYSTA is left out for more than 12 hours.
- Keep out of the reach of children.

Important Warnings

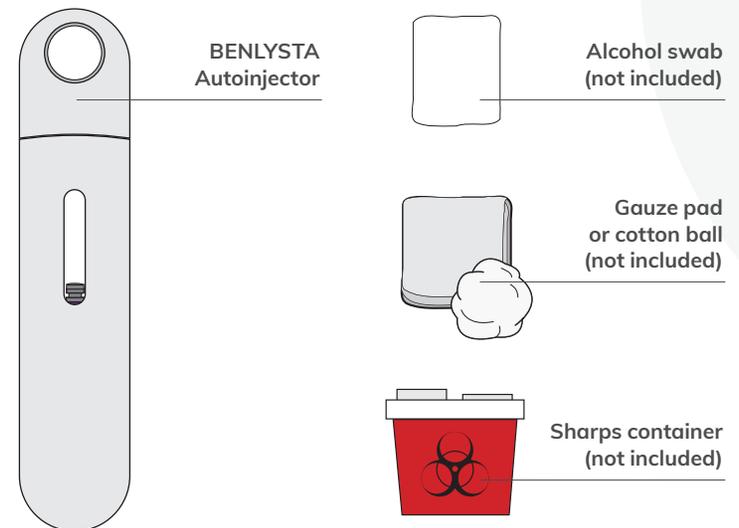
- The Autoinjector should be used only 1 time and then thrown away. See page 9, "Dispose of used Autoinjector and inspect."
 - Do not share your BENLYSTA Autoinjector with other people.
 - Do not shake the Autoinjector.
 - Do not use if dropped onto a hard surface.
 - Do not remove the Ring Cap until right before the injection.

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BENLYSTA (BELIMUMAB) AUTOINJECTOR PARTS



Supplies needed for the injection



STEP 1

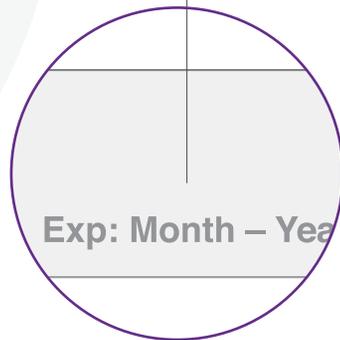
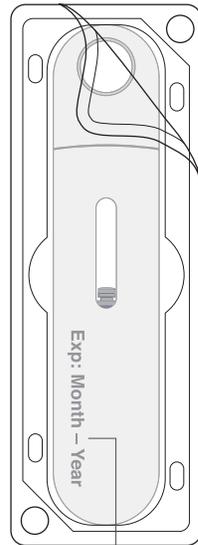
GATHER AND CHECK SUPPLIES

Gather supplies

- Remove 1 sealed tray containing an Autoinjector from the refrigerator.
- Find a comfortable, well-lit, and clean surface, and place the following supplies within reach:
 - BENLYSTA (belimumab) Autoinjector
 - Alcohol swab (not included)
 - Gauze pad or cotton ball (not included)
 - Sharps container (not included)
- **Do not** perform the injection if you do not have all the supplies listed.

Check expiration date

- Peel back the film of the tray and remove the Autoinjector.
- Check the expiration date on the Autoinjector.
- **Do not** use if the expiration date has passed.

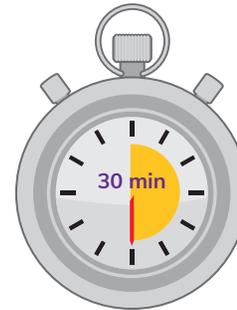


STEP 2

PREPARE AND INSPECT THE BENLYSTA (BELIMUMAB) AUTOINJECTOR

Allow to come to room temperature

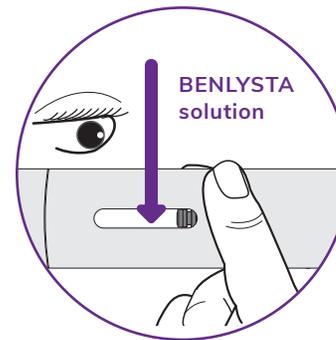
- Allow the Autoinjector to sit at room temperature for 30 minutes.
- **Do not** warm the Autoinjector in any other way. For example, do not warm in a microwave oven, hot water, or in direct sunlight.
- **Do not** remove the Ring Cap during this step.



Wait 30 minutes

Inspect BENLYSTA solution

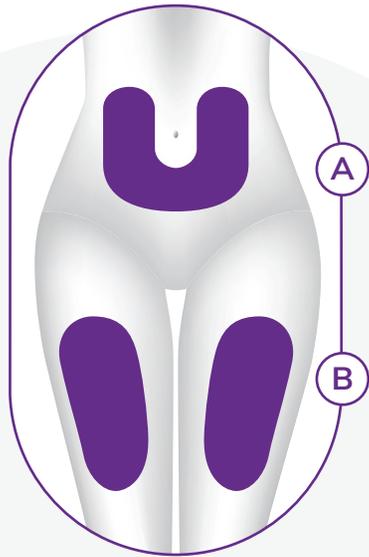
- Look in the Inspection Window to check that the BENLYSTA solution is colorless to slightly yellow in color.
- It is normal to see 1 or more air bubbles in the solution.
- **Do not** use if the solution looks cloudy, discolored, or has particles.



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STEP 3

CHOOSE AND CLEAN THE INJECTION SITE



Choose the injection site

- Choose where to inject (abdomen [A] or thigh [B]).
- If you need 2 injections to complete your dose, leave at least 2 inches between each injection if using the same site.
- Avoid injecting into the same site each time or in areas where the skin is tender, bruised, red, or hard.
- **Do not** inject within 2 inches of the belly button.



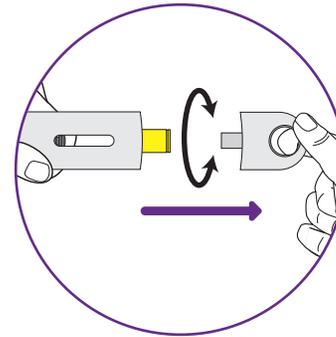
Clean the injection site

- Wash your hands.
- Clean the injection site by wiping it with an alcohol swab. Allow the skin to air dry.
- **Do not** touch this area again before giving the injection.

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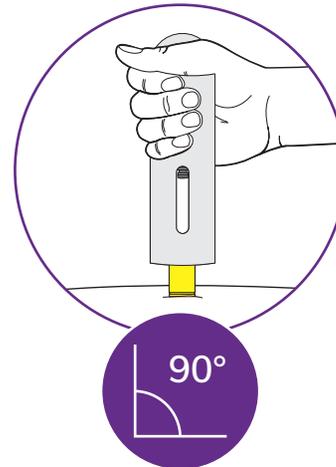
STEP 4

PREPARE FOR INJECTION



Remove the Ring Cap

- **Do not** remove the Ring Cap until right before you give the injection.
- Remove the Ring Cap by pulling or twisting it off. The Ring Cap may be twisted off in either a clockwise or counterclockwise direction.
- **Do not** put the Ring Cap back onto the Autoinjector.

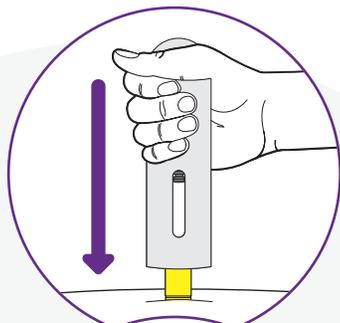


Position the Autoinjector

- Hold the Autoinjector comfortably so that you can see the Inspection Window. It is important that you can look at the Inspection Window while giving the injection. You will look at the Inspection Window to:
 - See that the Purple Indicator is moving while you are injecting.
 - See that the Purple Indicator has stopped to make sure that the dose is complete.
- Position the Autoinjector straight over the injection site at a 90-degree angle. Make sure the Gold Needle Guard is flat on the skin.

STEP 5

INJECT BENLYSTA (BELIMUMAB)



Start the injection

- Firmly press the Autoinjector all the way down onto the injection site and hold in place.
- This will insert the needle and start the injection.
- You may hear a “first click” at the start of the injection and see the Purple Indicator start to move through the Inspection Window.

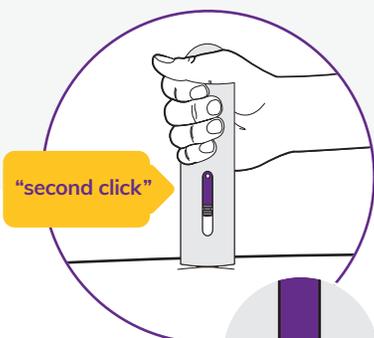


Purple Indicator



Complete the injection

- **Continue to hold the Autoinjector down until you see that the Purple Indicator has stopped moving.**
- You may hear a “second click” a few seconds before the Purple Indicator stops moving.
- The injection may take up to 15 seconds to complete.
- When the injection is complete, lift the Autoinjector from the injection site.



Then wait until Purple Indicator stops moving



STEP 6

DISPOSE OF USED AUTOINJECTOR AND INSPECT

Dispose of the used Autoinjector

Throw away (dispose of) the used Autoinjector and Ring Cap in a sharps container.

- Put your used Autoinjector in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) in your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that:
 - is made of a heavy-duty plastic;
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out;
 - is upright and stable during use;
 - is leak-resistant; and
 - is properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.



NOTE: STEP 6 is continued on the back cover of this tool.

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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?

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 patients with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines. BENLYSTA is also used to treat adult patients with active lupus nephritis (lupus-related kidney inflammation) who are receiving other lupus medicines. Both intravenous and subcutaneous dosing of BENLYSTA are approved for adults with SLE and lupus nephritis. Intravenous dosing of BENLYSTA is approved in children aged 5 years and older with SLE.

It is not known if BENLYSTA is safe and effective in people with severe active central nervous system lupus.

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. 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, 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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STEP 6 (CONT'D)

Inspect the injection site

- There may be a small amount of blood at the injection site. If needed, press a cotton ball or gauze pad on the injection site.
- **Do not** rub the injection site.

Additional information

For more information about BENLYSTA, go to www.BENLYSTA.com or call 1-877-423-6597.

Please see accompanying full Prescribing Information, including Medication Guide, for BENLYSTA.

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) 
Subcutaneous Use 200 mg/mL