Instructions for Use
BENLYSTA (ben-LIST-ah)
(belimumab)
Injection, for subcutaneous use
Prefilled Syringe

Read this Instructions for Use before you start to use BENLYSTA and each time you refill your prescription. There may be new information. You should also receive training from your healthcare provider on how to use the prefilled syringe the right way. If you do not follow these instructions the prefilled syringe 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 prefilled syringe should be used only 1 time and then thrown away. See below, “Dispose of used prefilled syringe and inspect.”
  - Do not share your BENLYSTA prefilled syringe with other people. You may give other people a serious infection, or get a serious infection from them.
  - Do not shake the prefilled syringe.
  - Do not use if dropped onto a hard surface.
  - Do not remove the Needle Cap until right before the injection.

BENLYSTA Prefilled Syringe Parts

Before use
- Needle
- Inspection Window
- Plunger
- Finger Grips
- Body

After Use
- Needle is covered by Needle Guard

Supplies needed for the injection
- BENLYSTA Prefilled Syringe
- Alcohol Swab (not included)
- Gauze Pad or Cotton Ball (not included)
- Sharps Container (not included)

1 Gather and check supplies
- Remove 1 sealed tray containing a prefilled syringe from the refrigerator.
- Find a comfortable, well-lit, and clean surface and place the following supplies within reach:
  - BENLYSTA Prefilled Syringe
  - 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.

2 Prepare and inspect the BENLYSTA Prefilled Syringe
- Allow to come to room temperature
  - Do not warm the prefilled syringe in any other way. For example, do not warm in a microwave oven, hot water, or in direct sunlight.
  - Do not remove the Needle Cap during this step.
- Inspect BENLYSTA solution
  - Do not use if the expiration date has passed.

3 Wait
- Allow the prefilled syringe to sit at room temperature for 30 minutes. See Figure B.
  - Do not warm the prefilled syringe in any other way. For example, do not warm in a microwave oven, hot water, or in direct sunlight.
  - Do not remove the Needle Cap during this step.
- Inspect BENLYSTA solution
  - Look in the Inspection Window to check that the BENLYSTA solution is colorless to slightly yellow in color. See Figure C.
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• 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.

3 Choose and clean the injection site

Choose the injection site
• Choose where to inject (abdomen or thigh). See Figure D.
• Avoid injecting into the same site each time or in areas where the skin is tender, bruised, red, or hard.

Clean the injection site
• Wash your hands.
• Clean the injection site by wiping it with an Alcohol Swab. Allow the skin to air dry. See Figure E.

• Do not inject within 2 inches of the belly button.

4 Prepare for the injection

Remove the Needle Cap
• Do not remove the Needle Cap until right before you give the injection.
• Hold the prefilled syringe by the body and with the Needle facing away from you. Remove the Needle Cap by pulling it straight off. See Figure F.

• You may see a drop of liquid at the end of the Needle. This is normal.
• Do not let the Needle touch any surface.
• Do not push any air bubbles out of the prefilled syringe.
• Do not put the Needle Cap back onto the prefilled syringe.
• Keep your hands away from the Plunger to avoid pushing it before injecting.

5 Inject BENLYSTA

Insert the Needle
• Hold the prefilled syringe in one hand and use your free hand to gently pinch the skin around the injection site. See Figure G.
• Insert the entire Needle into the pinched area of the skin at a slight 45-degree angle using a dart-like motion.

Complete the injection
• Push the Plunger all the way down until all of the solution is injected. See Figure H.
• After the Needle is completely inserted, release the pinched skin.

• While keeping your hold on the syringe, slowly move your thumb back, allowing the Plunger to rise up. The Needle will automatically rise up into the Needle Guard. See Figure I.
Dispose of the used prefilled syringe and inspect

Throw away (dispose of) the used syringe and Needle Cap in a Sharps Container. See Figure J.

- Put your used syringe and sharps in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a 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
  - 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 sharps disposal 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.

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.

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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 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. See Figure A.
- Do not use if the expiration date has passed.

2 Prepare and inspect the BENLYSTA Autoinjector

Allow to come to room temperature
- Allow the autoinjector to sit at room temperature for 30 minutes. See Figure B.
  - 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.

Inspect BENLYSTA solution
- Look in the Inspection Window to check that the BENLYSTA solution is colorless to slightly yellow in color. See Figure C.
  - 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.

3 Choose and clean the injection site

Choose the injection site
- Choose where to inject (abdomen or thigh). See Figure D.
- 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. See Figure E.
- Do not touch this area again before giving the injection.

4 Prepare for the 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 counter-clockwise direction. See Figure F.
- Do not touch this area again before giving the injection.
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**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.
See Figure G.

**Start the injection**
- Firmly press the autoinjector all the way down onto the injection site and hold in place. See Figure H.
- This will insert the needle and start the injection.

**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. See Figure J.

**Dispose of used autoinjector and inspect**
- The injection may take up to 15 seconds to complete.
- When the injection is complete, lift the autoinjector from the injection site.

**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.

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