

INSTRUCTIONS FOR USE
ZINBRYTA® (zin-bry-tuh)
(daclizumab)
Injection, for Subcutaneous Use
Single-Dose Prefilled Syringe
150 mg

Read this Instructions for Use before you start using ZINBRYTA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Important information:

- **Before you use ZINBRYTA for the first time**, your healthcare provider should show you or your caregiver how to prepare and inject your ZINBRYTA prefilled syringe the right way.
- ZINBRYTA is for use under the skin only (subcutaneous).
- **ZINBRYTA prefilled syringe is for 1 time use only. Do not** share your ZINBRYTA prefilled syringe with other people. You may give an infection to them or get an infection from them.
- Throw away (dispose of) the ZINBRYTA prefilled syringe right away after use. See **“Disposing of ZINBRYTA prefilled syringes”** at the end of this Instructions for Use.

Supplies needed for your ZINBRYTA prefilled syringe injection (See Figure A):

- a ZINBRYTA 150 mg prefilled syringe

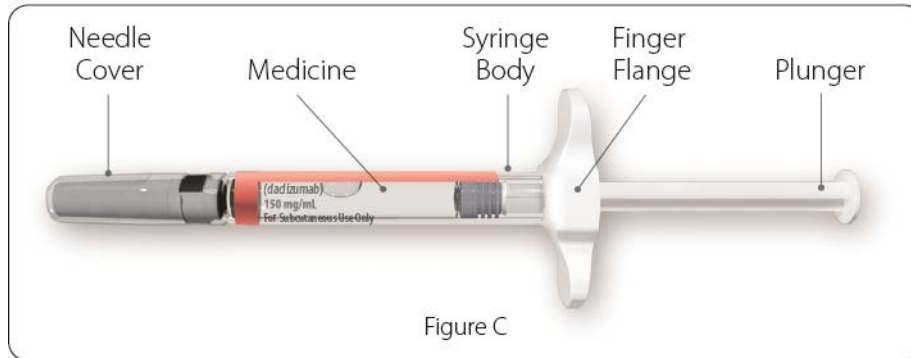


Additional supplies you will need for your injection (See Figure B):

- alcohol wipe
- gauze pad
- adhesive bandage
- 1 sharps container for throwing away ZINBRYTA prefilled syringes. See **“Disposing of ZINBRYTA prefilled syringes”** at the end of these instructions.
- a well-lit area and a clean, flat surface to work on, like a table



Parts of your ZINBRYTA prefilled syringe (See Figure C):



- **Before you prepare your injection, take your ZINBRYTA prefilled syringe out of the refrigerator and let it come to room temperature for at least 30 minutes.**
 - **Do not** use external heat sources such as hot water to warm the ZINBRYTA prefilled syringe.
- **Do not** use more than 1 prefilled syringe each month.
- The finger flange will allow you to hold the prefilled syringe more firmly. **Do not** remove the finger flange.

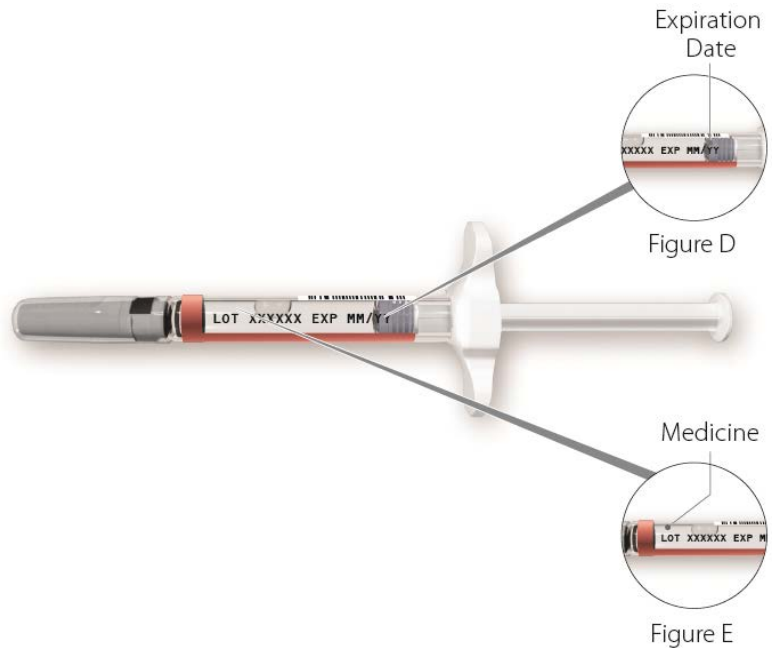
Preparing for your injection:

Step 1: Collect your supplies and wash your hands

- Find a well-lit and clean, flat surface, like a table and collect all the supplies you will need to give yourself or to receive an injection.
- Wash your hands with soap and water and dry your hands well.

Step 2: Check your ZINBRYTA prefilled syringe

- Check the expiration date printed on your ZINBRYTA prefilled syringe (**See Figure D**).
 - **Do not** use ZINBRYTA prefilled syringe past the expiration date.
- Check that your ZINBRYTA medicine is clear and colorless to slightly yellow (**See Figure E**).
 - **Do not** use ZINBRYTA prefilled syringe if the liquid is cloudy, or has floating particles in it.
 - You might see air bubbles in your ZINBRYTA medicine. This is normal and will not affect your dose.



Giving your injection:

Step 3: Choose and clean your injection site

- ZINBRYTA prefilled syringe is used to inject ZINBRYTA under the skin only (subcutaneous).
- ZINBRYTA prefilled syringe should be injected into the thigh, abdomen, or the back of the upper arm (**See Figure F**).
 - **Do not** inject directly into your belly button.
 - **Do not** inject into an area of the body where the skin is irritated, tender, red, bruised, infected, scarred, or tattooed.
- Choose an injection site and wipe the skin with an alcohol wipe.
- Let the injection site dry before injecting the dose.
 - **Do not** touch this area again before giving the injection.
- Do not take off the ZINBRYTA prefilled

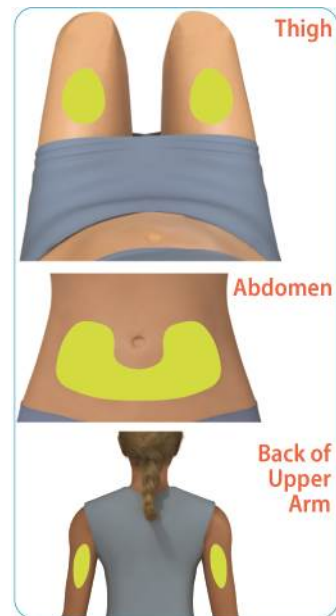
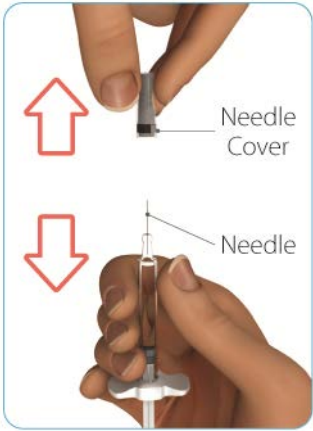

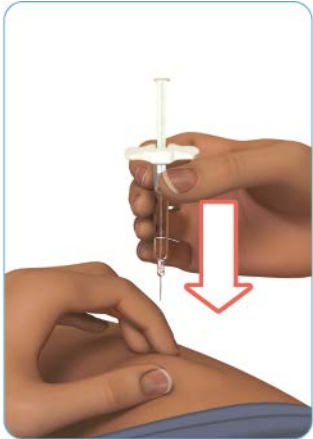


Figure F

<p>syringe needle cover until you are ready to inject.</p>	
<p>Step 4: Remove the ZINBRYTA prefilled syringe needle cover</p>	
<ul style="list-style-type: none"> • With 1 hand, hold your ZINBRYTA prefilled syringe as shown. Do not push on the finger flange. With your other hand, firmly hold the needle cover and pull the needle cover straight off the needle (See Figure G). <ul style="list-style-type: none"> ○ Throw away the needle cover after your injection. Do not recap your ZINBRYTA prefilled syringe, you could get a needle stick injury. ○ Do not touch the needle. 	 <p style="text-align: center;">Figure G</p>
<p>Step 5: Give your ZINBRYTA prefilled syringe injection</p>	
<ul style="list-style-type: none"> • With 1 hand, use your thumb and first finger and pinch the skin around the cleaned injection site (See Figure H). 	 <p style="text-align: center;">Figure H</p>
<ul style="list-style-type: none"> • With your other hand, hold your ZINBRYTA prefilled syringe like a pencil. Use a quick dart-like motion and insert the needle at a 90° angle into your skin (See Figure I). • After the needle is in, let go of your skin 	 <p style="text-align: center;">Figure I</p>
<ul style="list-style-type: none"> • Slowly push the plunger down until the syringe is empty (See Figure J). 	

- **Do not** pull back on the plunger.
- **Do not** take your ZINBRYTA prefilled syringe out of your skin until you have slowly pushed the plunger all the way down.



Figure J

Step 6: Remove the ZINBRYTA prefilled syringe from your injection site

- Pull the needle straight out of your skin (**See Figure K**).
 - If you see blood at your injection site, wipe it off with gauze and apply an adhesive bandage.
- **Do not** recap the ZINBRYTA prefilled syringe. Recapping the prefilled syringe can lead to a needle stick injury.
- **Do not** reuse the ZINBRYTA prefilled syringe.



Figure K

After your injection:

Step 7: Disposing of ZINBRYTA prefilled syringes

- Put your used ZINBRYTA prefilled syringes in a FDA-cleared sharps disposal container right away after use (**see Figure L**). **Do not throw away (dispose of) loose needles and ZINBRYTA prefilled 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



Figure L

<p>being able to come out,</p> <ul style="list-style-type: none"> ○ upright and stable during use, ○ leak resistant, and ○ properly labeled to warn of hazardous waste inside the container. <ul style="list-style-type: none"> ● 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 the FDA's website at: 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. 	
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How should I store ZINBRYTA Prefilled Syringe?

- Store ZINBRYTA prefilled syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze ZINBRYTA prefilled syringe or expose to temperatures above 86°F (30°C). **Do not** use ZINBRYTA prefilled syringe that has been frozen.
- Keep ZINBRYTA prefilled syringe in the original carton to protect it from light.
- If you cannot refrigerate ZINBRYTA prefilled syringe, you can store ZINBRYTA at room temperature for up to 30 days.
- If ZINBRYTA prefilled syringe has reached room temperature, **do not** put it back in the refrigerator.
- **Keep ZINBRYTA prefilled syringe and all medicines out of the reach of children.**

Questions?

For product or service related questions, please call 1-800-456-2255 or go to www.Zinbryta.com.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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