INSTRUCTIONS FOR USE
OMLYCLO® [OM-ly-clo]
(omalizumab-igec)
injection, for subcutaneous use
Single-Dose Prefilled Syringe

Read and follow the Instructions for Use that come with your Omlyclo Prefilled Syringe before you start using it and each time you get a refill. There may be new information. Before you use Omlyclo Prefilled Syringe for the first time, make sure your healthcare provider shows you the right way to use it.

Do not use OMLYCLO for the emergency treatment of any allergic reactions, including anaphylaxis, hives or sudden breathing problems.

For children 12 years of age and older, OMLYCLO Prefilled Syringe may be self-injected under adult supervision. For children 1 to 11 years of age, OMLYCLO Prefilled Syringe should be injected by a caregiver and healthcare provider.

Parts of the Prefilled Syringe (see Figure A)

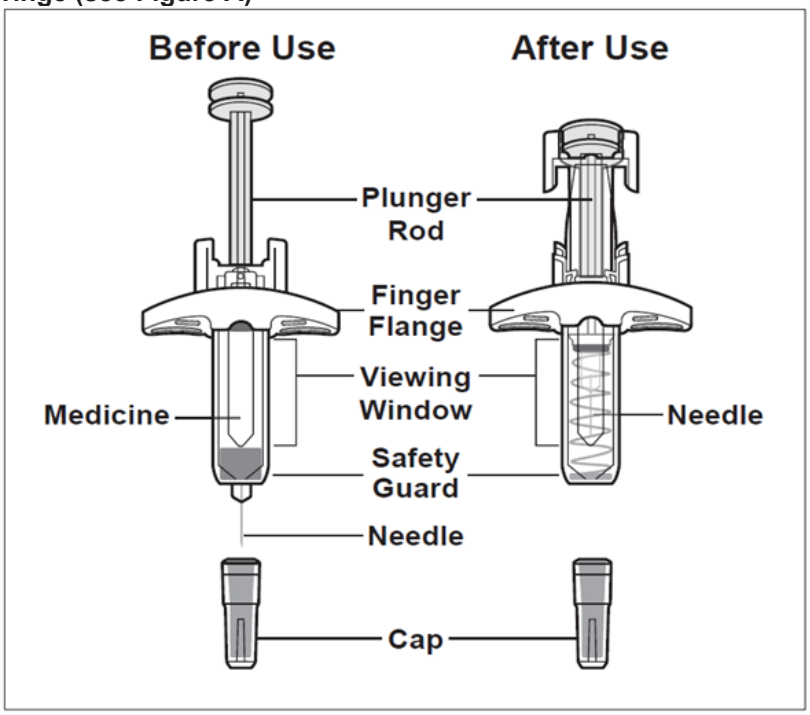

Figure A

Choose the Correct Prefilled Syringe or Combination of Prefilled Syringes

Omlyclo Prefilled Syringes are available in **3 dose strengths** (see **Figure B**). **These instructions are to be used for all dose strengths.**

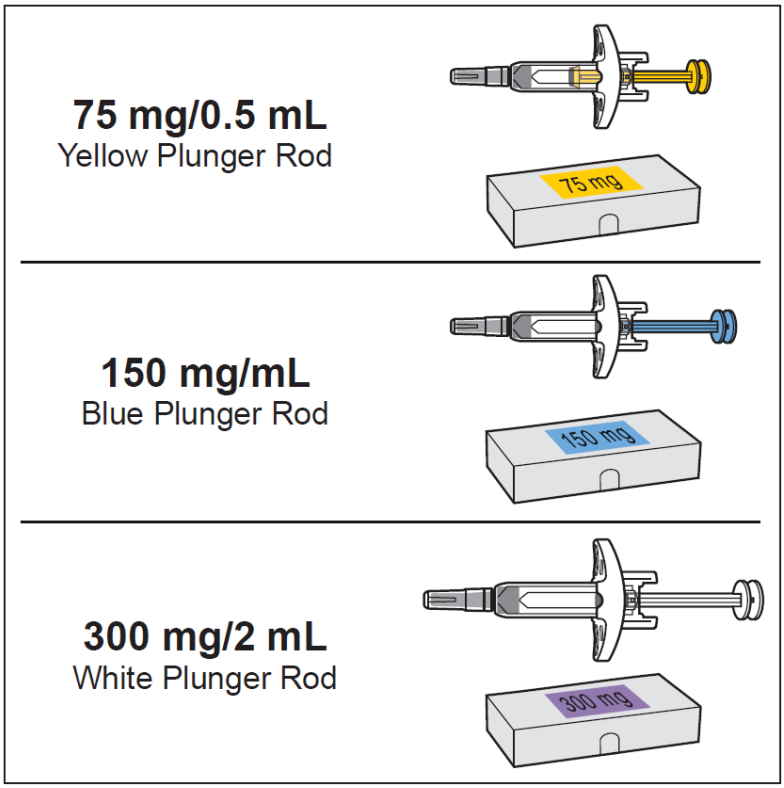

Figure B

Your prescribed dose may require more than 1 injection. **The Dosing Table** (**Figure C**) below shows the combination of Prefilled Syringes needed to give your full dose. Check the label on the Omlyclo carton to make sure you have received the correct Prefilled Syringe or combination of Prefilled Syringes for your prescribed dose. If your dose requires more than 1 injection, complete all injections for your prescribed dose, immediately one after another. Contact your healthcare provider if you have any questions.

Dosing Table

Dose	Syringes recommended for dose	Yellow Plunger Rod (75 mg)	Blue Plunger Rod (150 mg)	White Plunger Rod (300 mg)
75 mg	1 yellow			
150 mg	1 blue			
225 mg	1 yellow + 1 blue			
300 mg	1 white			
375 mg	1 yellow + 1 white			
450 mg	1 blue + 1 white			
525 mg	1 yellow + 1 blue + 1 white			
600 mg	2 white			

Figure C

Note: Your healthcare provider may prescribe a different combination of Prefilled Syringes for your complete dose.

How Should I Store OMLYCLO?

- Store the unused Prefilled Syringe in the original carton and store the carton in a refrigerator between 36°F to 46°F (2°C to 8ºC).
- **Do not** remove the Prefilled Syringe from its original carton during storage.
- Keep the Prefilled Syringe out of direct light.
- **Do not** freeze.
- **Do not** use if the Prefilled Syringe has been frozen.
- Before giving an injection, the carton can be removed from and placed back in the refrigerator if needed. The total combined time out of the refrigerator may not exceed 7 days. If the Prefilled Syringe is exposed to temperatures above 77ºF (25°C), **do not** use it and throw away in a FDA-cleared sharps disposal container.
- **Keep the Prefilled Syringe, and all medicines out of reach of children. Prefilled Syringe contains small parts.**

Important information

- **Do not** open the sealed carton until you are ready to inject the Prefilled Syringe.
- **Do not** use if the carton or the Prefilled Syringe is damaged or appears to be tampered with.
- **Do not** take the Cap off until you are ready to inject the Prefilled Syringe.
- **Do not** use if the Prefilled Syringe has been dropped on a hard surface or dropped after removing the Cap.
- **Do not** reuse the same Prefilled Syringe.
- **Do not** leave the Prefilled Syringe unattended.
- **Do not** try to take the Prefilled Syringe apart at any time.

Preparing for the Injection

1. Take the carton containing the Prefilled Syringe out of the refrigerator.

1a. If you need more than 1 Prefilled Syringe to deliver your prescribed dose (see **Figure C**), take all the cartons out of the refrigerator at the same time (each carton contains 1 Prefilled Syringe). The following steps must be followed for each Prefilled Syringe.

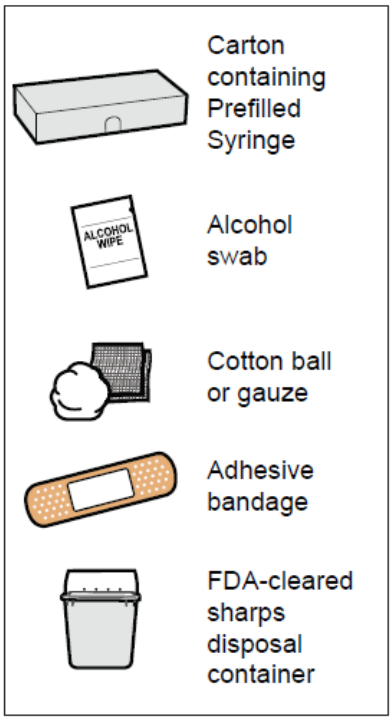

Figure D

2. Gather the supplies needed to give your injection (see Figure D).

- Carton containing Prefilled Syringe

Not included in the carton:
- Alcohol swab
- Cotton ball or gauze
- Adhesive bandage
- FDA-cleared Sharps disposal container

Note: You may need more than 1 Prefilled Syringe for your prescribed dose. See the **Dosing Table (Figure C) above** for more information. Each carton contains 1 Prefilled Syringe.

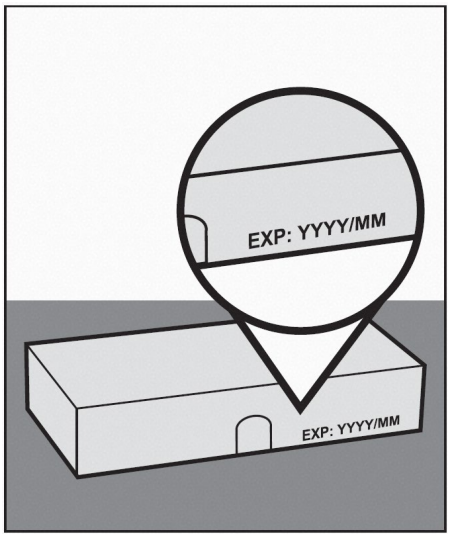

Figure E

3. Check the expiration on the carton (see Figure E).

- **Do not** use it if the expiration date has passed.
- If the expiration date has passed, safely dispose of the carton in a FDA-cleared sharps disposal container (see **Step 17. Dispose of the Prefilled Syringe**) and contact your healthcare provider.

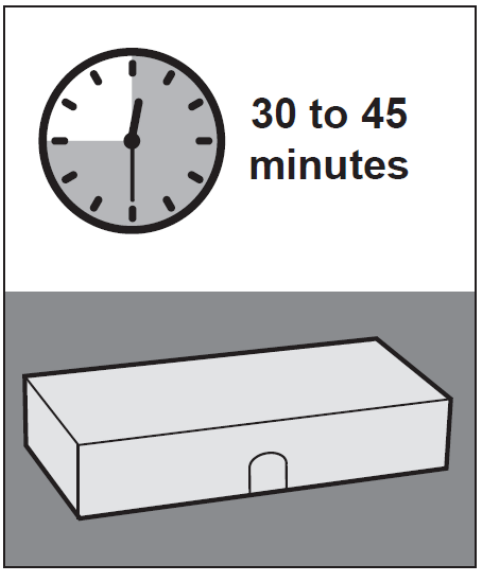

Figure F

4. Allow the Prefilled Syringe to reach room temperature.

4a. Set aside the unopened carton on a clean, flat surface for at least 30 to 45 minutes to allow it to warm up. Leave the Prefilled Syringe in the carton to protect it from light (see **Figure F***).*

- **Do not** warm the Prefilled Syringe using heat sources such as hot water or a microwave.
- If the Prefilled Syringe does not reach room temperature, this could cause the injection to feel uncomfortable and make it hard to push the Plunger rod.

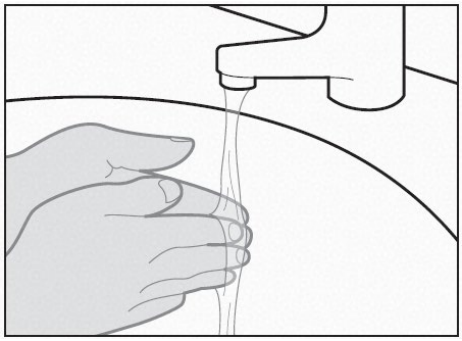

Figure G

5. Wash your hands.

5a. Wash your hands with soap and water and dry them thoroughly (see **Figure G**).

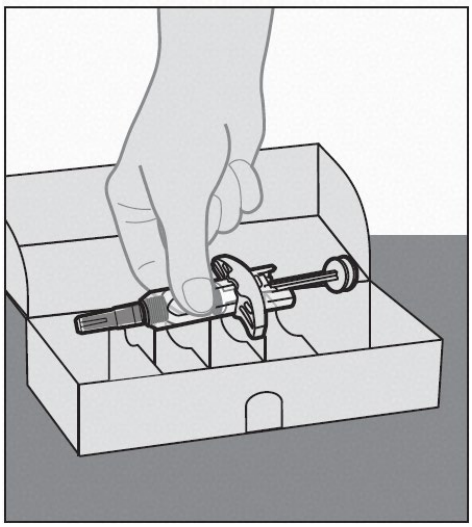

Figure H

6. Remove the Prefilled Syringe from the carton.

6a. Open the carton.

6b. Gripping from the syringe body lift the Prefilled Syringe from the carton (see **Figure H**).

- **Do not** touch the Plunger rod or Cap when removing the Prefilled Syringe from the carton.
- **Do not** flip the carton upside down to take out the Prefilled Syringe.

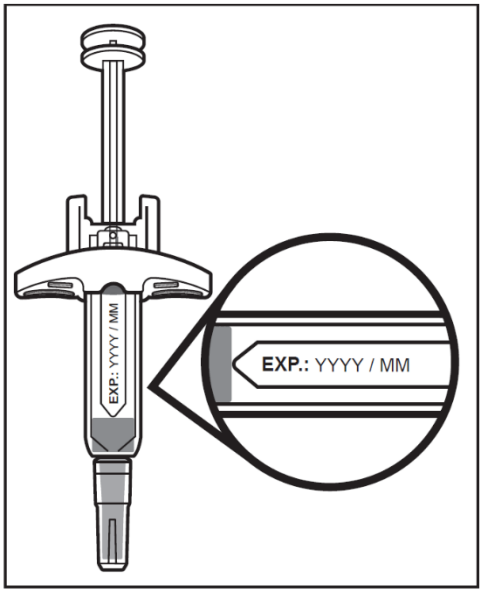

Figure I

7. Inspect the Prefilled Syringe.

7a. Look at the Prefilled Syringe and make sure you have the correct medicine (OMLYCLO) and dosage.

7b. Look at the Prefilled Syringe and make sure it is not cracked or damaged, or has been tampered with.

- **Do not** use if the Prefilled Syringe is cracked, damaged or appears to be tampered with.

7c. Check the expiration date on the label of the Prefilled Syringe (see **Figure I**).

- **Do not** use if the expiration date has passed.

Note: If the expiration date is not visible in the viewing window, rotate the plunger rod of the Prefilled Syringe until the expiration date becomes visible.

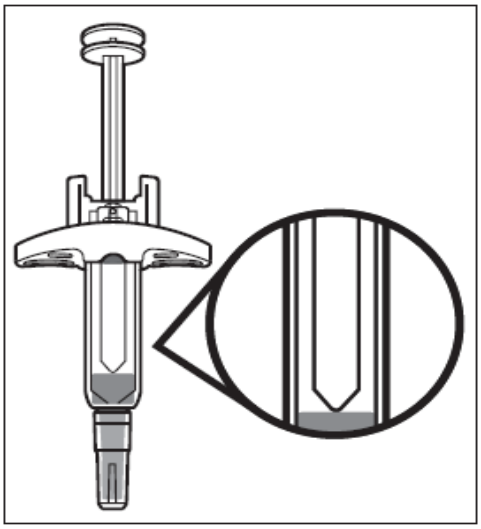

Figure J

8. Inspect the Medicine.

8a. Look at the Medicine and confirm that the liquid is clear to slightly cloudy, colorless to pale brownish-yellow, and free of particles (see **Figure J**).

- **Do not** use the Prefilled Syringe if the liquid is discolored, distinctly cloudy, or contains particles in it.
- You may see air bubbles in the liquid. This is normal.
- **Do not** try to remove the air bubbles.

8b. If the Medicine does not look as described or if the expiration date has passed, safely dispose of the Prefilled Syringe in a FDA-cleared sharps disposal container (see **Step 17**) and contact your healthcare provider.

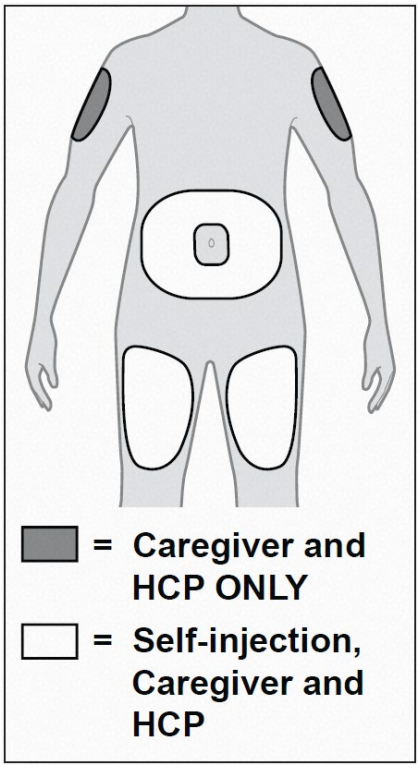

Figure K

9. Choose an injection site (see Figure K)

9a. If you are giving yourself the injection, you can inject into:

- The front of the thighs.
- The stomach area (abdomen) except within the 2-inch (5-cm) area around your belly button (navel).

9b. If a caregiver or Health Care Provider (HCP) is giving the injection, they can use:

- The outer area of the upper arm.
- The front of the thighs.
- The stomach area (abdomen) except within the 2-inch (5-cm) area around your belly button (navel).

- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard, or if there are breaks in the skin.
- **Do not** inject through clothing. The injection site should be exposed, clean skin.

9c. If your prescribed dose requires more than 1 injection, make sure your injections are at least 1 inch (2.5 cm) apart from each other.

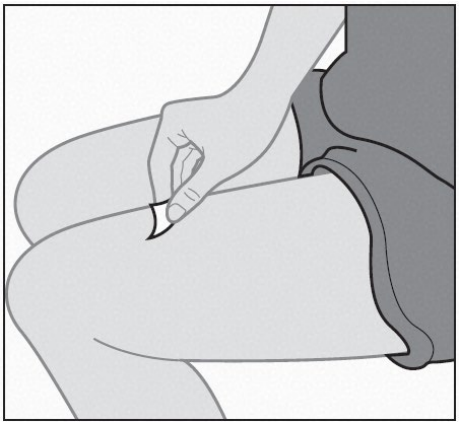

Figure L

10. Clean the injection site.

10a. Clean the injection site with an alcohol swab using a circular motion (see **Figure L**).

10b. Let the skin dry for 10 seconds before injecting.

- **Do not** fan or blow on the clean area.
- **Do not** touch the injection site again before giving the injection.

Giving the Injection

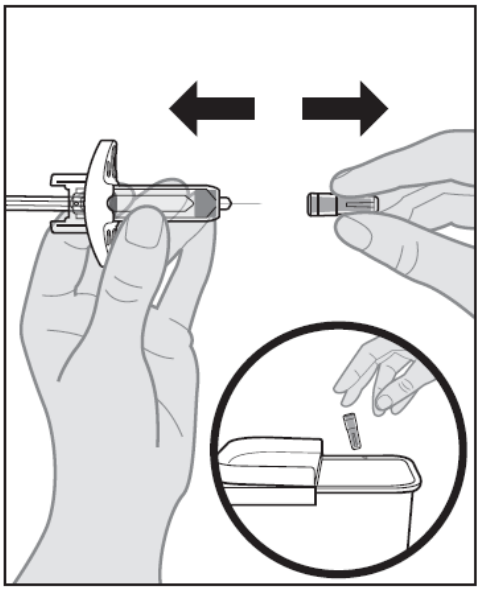

Figure M

11. Remove the Cap.

11a. Hold the Prefilled Syringe by the syringe body in one hand.

11b. Gently pull the Cap straight off with the other hand (See **Figure M**).

- **Do not** remove the Cap until you are ready to inject.
- **Do not** twist the Cap.
- **Do not** hold, push or pull the Plunger rod while removing the Cap.
- You may see a few drops of liquid at the tip of the Needle. This is normal.

11c. Dispose of the Cap right away in a FDA-cleared sharps disposal container (see **Step 17. Dispose of the Prefilled Syringe** and **Figure M**).

- **Do not** re-cap the Prefilled Syringe.
- **Do not** touch the Needle or let it touch any surfaces after removing the Cap.

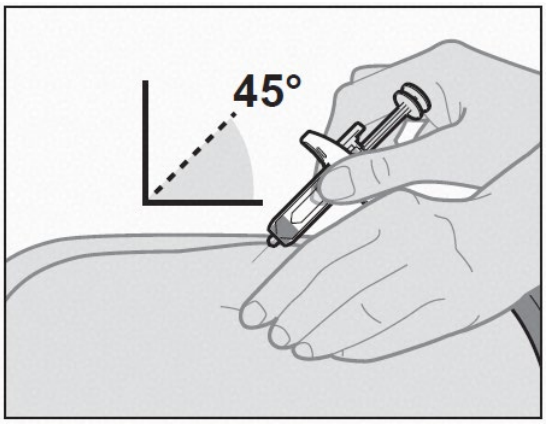

Figure N

12. Insert the Prefilled Syringe into the injection site.

12a. Gently pinch a fold of skin at the injection site with one hand. Hold the pinched skin tightly until the injection is complete.

Note: Pinching the skin is important to make sure that you inject under the skin (into the fatty area) but not any deeper (into muscle).

12b. With a quick and “dart-like” motion, insert the Needle all the way into the pinched skin at an angle of about 45 -degrees (see **Figure N**).

Note: It is important to use the correct angle to make sure the Medicine is delivered under the skin (into the fatty area), or the injection could be uncomfortable and the Medicine may not work.

- **Do not** touch the Plunger rod while inserting the Needle into the skin.
- **Do not** insert the needle through clothing.
- Hold the Prefilled syringe tightly in place and **do not** change the angle of injection or insert the Needle again. **Do** not move and avoid sudden movements throughout the injection.

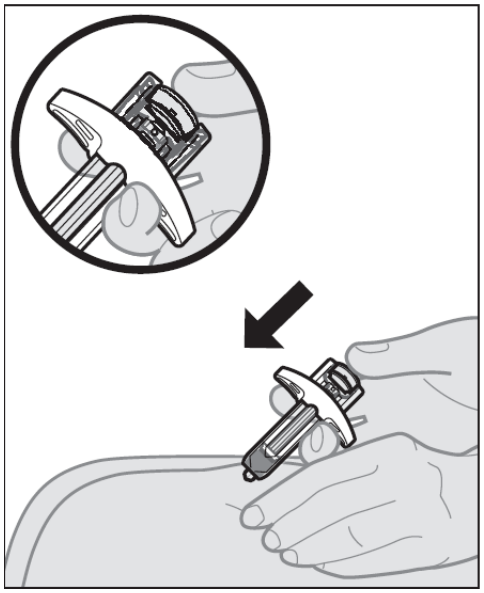

Figure O

13. Give the injection.

13a. Slowly push the Plunger rod **all the way down** until the full dose of medicine gets injected, and the syringe is empty (see **Figure O**).

- **Do not** change the position of the Prefilled Syringe after the injection has started.
- If the Plunger rod is not fully pressed, the Safety Guard will not extend to cover the Needle when it is removed.

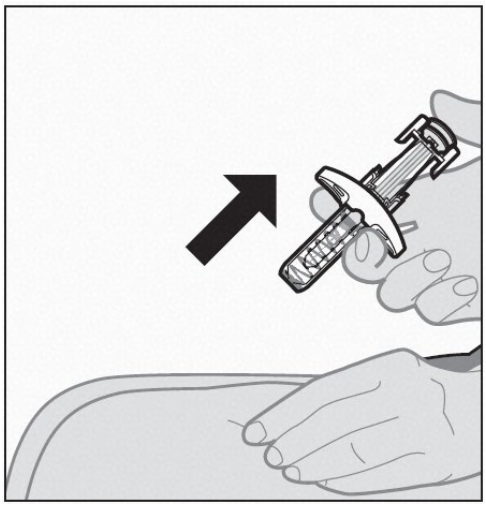

Figure P

14. Remove the Prefilled Syringe from the injection site.

14a. After the Prefilled Syringe is empty, slowly lift your thumb from the Plunger rod until the Needle is completely covered by the Safety Guard (see **Figure P**).

- If the Needle is not covered, carefully remove the Prefilled Syringe from the skin and dispose of the Prefilled Syringe in a FDA-cleared sharps disposal container (see **Step 17. Dispose of the Prefilled Syringe**).

14b. Remove the Prefilled Syringe from the injection site and release the pinch.

- Some bleeding may occur (see **Step 15. Care for the injection site**).
- **Do not** reuse the Prefilled Syringe.

15. Care for the injection site.

15a. If some bleeding occurs or there is a drop of liquid at the injection site, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.

- **Do not** rub the injection site.

15b. In case of skin contact with Medicine, wash the area that touched the Medicine with water.

16. If your prescribed dose requires more than 1 injection:

16a. Throw away the used Prefilled Syringe as described in **Step 17. Dispose of the Prefilled Syringe**.

16b. Repeat **Step 2** through **Step 15** for the next injection using a new Prefilled Syringe.

- Make sure each injection is **at least 1 inch (2.5 cm)** apart from each other.
- Complete all the required injections for your prescribed dose, immediately one after another.
- Contact your healthcare provider if you have any questions.

After the injection

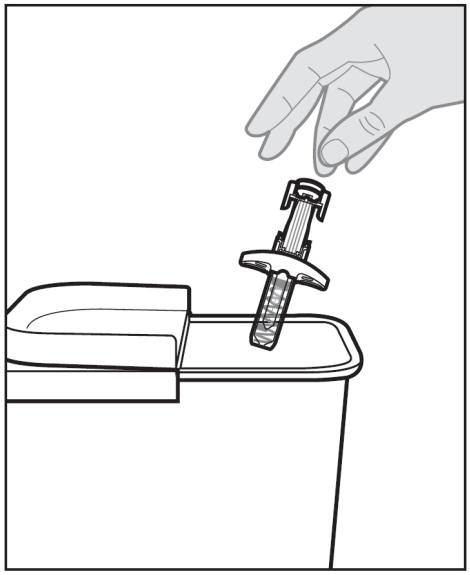

Figure Q

17. Dispose of the Prefilled Syringe.

17a. Put the used Prefilled Syringe in a FDA-cleared sharps disposal container right away after use (see **Figure Q**).

- The OMLYCLO Prefilled Syringe is a single dose syringe and should not be used again.
- **Do not** re-cap the Prefilled Syringe.
- **Do not** throw away (dispose of) the Prefilled Syringe 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,
- upright and stable during use,
- 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 it. 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.

This Instructions for Use has been approved by the U.S. Food and Drug Administration 12/2025

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