

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **Omlyclo**[®]

Omalizumab injection - solution for subcutaneous injection

This Patient Medication Information is written for the person who will be taking **Omlyclo**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **Omlyclo**, talk to a healthcare professional.

Omlyclo is a biosimilar biologic drug (biosimilar) to the reference biologic drug Xolair. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale in Canada.

Serious Warnings and Precautions

A severe allergic reaction called anaphylaxis can happen in some patients after receiving Omlyclo. Anaphylaxis is a life-threatening condition. Signs and symptoms of anaphylaxis include difficulty breathing, light-headedness, rash, itching, and swelling of the tongue and throat (see “Look out for signs of allergic reactions and other serious side effects” section).

Anaphylaxis from Omlyclo can happen as early as after the first injection or hours later, and/or after any Omlyclo injection. Your healthcare professional should watch you for some time for signs and symptoms of anaphylaxis after treatment is initiated. If you have any of the signs or symptoms of anaphylaxis, tell your doctor or nurse immediately, and get emergency medical treatment right away.

Your healthcare professional should instruct you about starting emergency medical treatment and getting further medical care if you have any signs or symptoms of anaphylaxis.

What Omlyclo is used for:

Asthma

Adults and adolescents 12 years of age and older:

Omlyclo is a prescription medicine. Omalizumab has been shown to significantly decrease the incidence of asthma exacerbations and improve control of asthma symptoms in people who:

- Are 12 years of age and above
- Have moderate to severe persistent asthma. This means they have 1 or more of the following:
 - Asthma symptoms every day
 - Daily need for a rescue inhaler

- 2 or more asthma attacks a week
- 1 or more nights a week waking up with asthma symptoms
- below-normal reading (less than 80%) from a tool called a peak flow meter, which measures how well the lungs work
- Have asthma that is triggered by year-round allergens in the air, which is confirmed by a doctor using a simple skin or blood test. This is known as allergic asthma
- Continue to have asthma symptoms even though they are taking inhaled steroids

Children 6 to less than 12 years of age:

Omlyclo is used as add-on therapy. Omalizumab has been shown to significantly decrease the rate of asthma exacerbations for children who are 6 to less than 12 years of age with moderate to severe persistent allergic asthma who continue to have asthma symptoms even though they are taking inhaled steroids and have a documented history of asthma exacerbation.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Omlyclo is used to treat adults (18 years of age and older) with chronic rhinosinusitis with nasal polyps (CRSwNP) whose disease is not well controlled with their current CRSwNP medicines. Omlyclo helps reduce the size of the polyps and improves symptoms caused by CRSwNP including nasal congestion, loss of sense of smell, post-nasal drip and runny nose.

Chronic Idiopathic Urticaria (CIU)

Omlyclo is a prescription medicine to treat Chronic Idiopathic Urticaria (CIU) in adults and adolescents (12 years of age and older) whose symptoms are not well controlled with antihistamines. Omlyclo provides relief of CIU symptoms such as skin itch and hives.

How Omlyclo works:

What is allergic asthma?

Allergic asthma is how doctors describe a particular type of asthma. In people with this common condition, certain types of allergens can trigger asthma attacks and symptoms, such as coughing, wheezing, and shortness of breath.

You probably know about many of the things that can trigger your asthma. Cat or dog dander, dust mites, and cockroaches are common examples of year-round allergens. What you may not know is how something as simple as visiting a friend who has a pet can lead to an asthma attack. The reason allergens can trigger asthma attacks is due, in part, to a body chemical called IgE.

What is Chronic Idiopathic Urticaria (CIU)

Chronic Idiopathic Urticaria (CIU) is a skin disease whose symptoms include itching and hives for at least 6 weeks. Persistent symptoms may be daily or episodic. Some people with CIU may also have swelling of the skin.

What is IgE?

IgE is short for immunoglobulin E. This substance, which occurs naturally in your body in small amounts, plays an important role in allergic asthma, CRSwNP and CIU.

If you have allergic asthma, your body makes more IgE when you breathe in an allergen that triggers

your asthma. This can cause a series of chemical reactions known as the “allergic-inflammatory process in allergic asthma”. It can result in 2 things:

- The muscles that surround your airways begin to tighten. This is known as *constriction of the airways*
- Your airways become irritated and swell up. This is known as *inflammation of the airways*

Together, constriction and inflammation of the airways make it harder for you to breathe. This can lead to an asthma attack, also known as exacerbation.

Asthma and Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Omyclo (omalizumab) blocks a substance called immunoglobulin E (also known simply as IgE) which is produced by your body. IgE contributes to a type of inflammation that plays a significant role in causing asthma and CRSwNP. Your doctor will measure the amount of IgE with a blood test and determine your body weight before starting the treatment with Omyclo. By blocking IgE, Omyclo helps stop the allergic-inflammatory process in allergic asthma.

Adding Omyclo injections to treatment with inhaled steroids has been clinically proven to help reduce the number of asthma attacks. Omyclo has not been proven to work in other allergic conditions.

Chronic Idiopathic Urticaria (CIU)

Omyclo(omalizumab) blocks a substance called immunoglobulin E (also known simply as IgE) which is produced by your body. By binding to IgE, Omyclo reduces the activation of certain cells in your body and the release of histamine and other chemicals. This helps reduce symptoms of CIU, including itching and hives.

The ingredients in Omyclo are:

Medicinal ingredient: Omalizumab

Non-medicinal ingredients: L-arginine hydrochloride, L- histidine, L-histidine hydrochloride monohydrate, polysorbate 20, water for injection.

Omyclo comes in the following dosage forms:

Omyclo is supplied as a ready to use solution in a pre-filled syringe or pre-filled pen. The pre-filled syringe or pre-filled pen are available in 75 mg, 150 mg and 300 mg of omalizumab.

Do not use Omyclo if:

- If you are hypersensitive (allergic) to omalizumab or any of the other ingredients of Omyclo (see above), or if you have ever had an allergic reaction to an Omyclo injection.

Omyclo’s needle cap is free of natural rubber latex or dry natural rubber.

Healthcare professionals should be aware that Omyclo utilizes a different color-coding system for dose identification compared to Xolair. Please ensure the correct dose is selected based on the specific color coding indicated on the packaging.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you

take Omlyclo. Talk about any health conditions or problems you may have, including if you:

- Hypersensitivity reaction to any drug (see above **Do not use Omlyclo if**)
- Any other known hypersensitivity (see above **Do not use Omlyclo if**)
- Any allergies to this drug or its ingredients or components of the container (see above **What are the ingredients in Omlyclo and Do not use Omlyclo if**)
- If you are living in a region where parasite infections are frequent or traveling to such a region, please tell your doctor. Omlyclo may weaken your resistance to such infections. If you are taking a treatment against parasite infection, please tell your doctor. Omlyclo may reduce the efficacy of your treatment.

Other warnings you should know about:

Omlyclo is not a rescue medicine and should not be used to treat sudden asthma attacks. It is not a substitute for the medicines you are already taking.

Weakness or paralysis of limbs or face, loss of sensation, difficulty speaking or understanding, transient loss of vision in one eye could be symptoms of a transient ischemic attack or stroke. Seek immediate medical attention if you experience any such symptoms.

Use in children

Allergic asthma: Omlyclo is not indicated for children below 6 years of age.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP): Omlyclo is not indicated for children below 18 years of age.

Chronic idiopathic urticaria (CIU): Omlyclo is not indicated for children below 12 years of age.

Omlyclo 300 mg pre-filled syringe and all dose strengths of Omlyclo pre-filled pens are not intended for use in children under 12 years of age. Omlyclo 75 mg pre-filled syringe and Omlyclo 150 mg pre-filled syringe may be used in children 6 to 11 years of age with allergic asthma.

Pregnancy

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Before starting treatment with Omlyclo, tell your doctor if you are pregnant or think that you may be pregnant. Your doctor will discuss with you the benefits and potential risks of being given this medicine during pregnancy. Tell your doctor straight away if you become pregnant while being treated with Omlyclo.

Breast-feeding

Ask your doctor, nurse or pharmacist for advice before being given any medicine.

Tell your doctor if you are breast-feeding. It is not known whether omalizumab, the active substance of Omlyclo, passes into breast milk or in what ways this could affect the baby. Your doctor will discuss with you the benefits and potential risks of being given this medicine while you are breast-feeding.

Fertility

There are no human fertility data for Omlyclo.

Driving and using machines

You may experience dizziness, sleepiness or fatigue after receiving Omlyclo, in which case you should not drive or use machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Omlyclo:

Please inform your doctor or nurse if you are taking or have recently taken any other medicines, even those not prescribed. Never suddenly stop taking, or change the dose of, your inhaled steroids or any other asthma medicine or of current medicine for CIU you are taking unless your doctor tells you to do so.

Omlyclo can be used together with other medicines for asthma and/or CRSwNP, as well as with H1 or H2 antihistamines and leukotriene receptor antagonists (LTRAs) for CIU, but it is still important to tell your doctor that you are taking them before you are given Omlyclo.

How to take Omlyclo:

Omlyclo is used as an injection under your skin (known as a subcutaneous injection).

Injecting Omlyclo pre-filled syringe and pre-filled pen

- You and your doctor will decide if you should inject Omlyclo yourself. The first 3 doses are given by or under the supervision of a healthcare professional (see [3 Serious Warnings and Precautions Box](#)).
- It is important to be properly trained on how to inject the medicine before injecting yourself.
- A caregiver (for example a parent) may also give you your Omlyclo injection after he or she has received proper training.

For detailed instructions on how to inject Omlyclo, see “**Instructions for use of Omlyclo pre-filled syringe**” or “**Instructions for use of Omlyclo pre-filled pen**” at the end of this section.

Training to recognize serious allergic reactions

It is also important that you do not inject Omlyclo yourself until you have been trained by your healthcare professional on:

- how to recognize the early signs and symptoms of serious allergic reactions.
- what to do if the signs occur.

For more information about the early signs and symptoms of serious allergic reactions, see “**Look out for signs of allergic reactions and other serious side effects**” section.

Asthma

Based on your dose, your doctor will also tell you if you will need 1, 2, or 3 injections per dose. If you need more than 1 injection per dose, each will be given in a different area of your body.

You will receive 75, 150, 225 or 300 mg every four weeks, or 225, 300 or 375 mg every two weeks. You will probably need to continue taking your current asthma medicine during Omlyclo treatment

but after 16 weeks you may be able to reduce or stop any other asthma medication that you are taking. Your doctor will discuss this with you. You should not reduce the dose of other asthma medication without first discussing with your doctor, even if you are feeling better.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

You will need 1 to 4 injections at a time. You will need the injections either every two weeks or every four weeks as prescribed by your doctor.

Keep taking your current CRSwNP medicine during Omlyclo treatment. Do not stop taking any CRSwNP medications without talking to your doctor.

Chronic Idiopathic Urticaria (CIU)

Omlyclo 150 mg or 300 mg are administered subcutaneously every 4 weeks. The efficacy of Omlyclo in CIU patients depends on the quantity that is injected.

INSTRUCTIONS FOR USE OF OMLYCLO PRE-FILLED SYRINGE

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

Children (6 to 11 years of age) should not inject Omlyclo Pre-filled Syringes themselves, however, if deemed appropriate by their healthcare provider, a caregiver may give them their injection after proper training.

Parts of the Pre-filled Syringe (see Figure A)

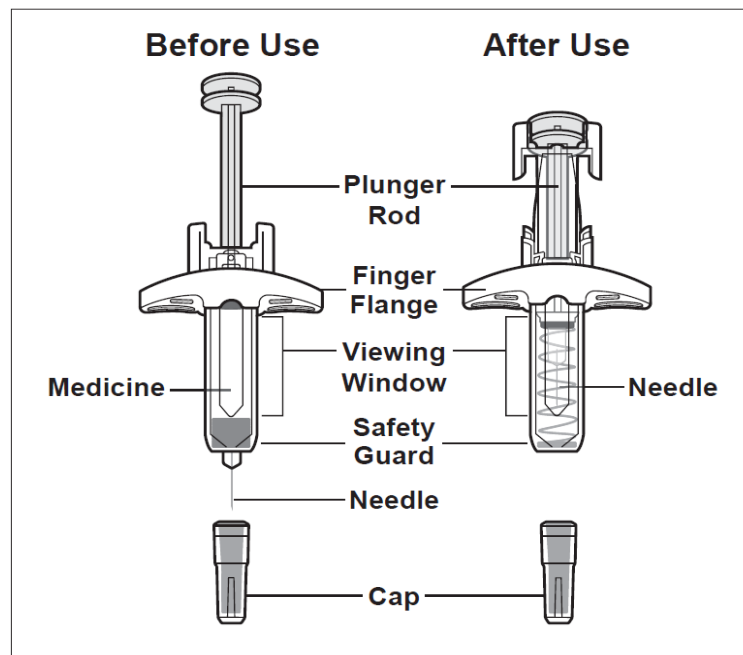


Figure A

Choose the Correct Pre-filled Syringe or Combination of Pre-filled Syringes

Omyclo Pre-filled Syringes are available in **3 dose strengths** (see **Figure B**). These instructions are to be used for all dose strengths.

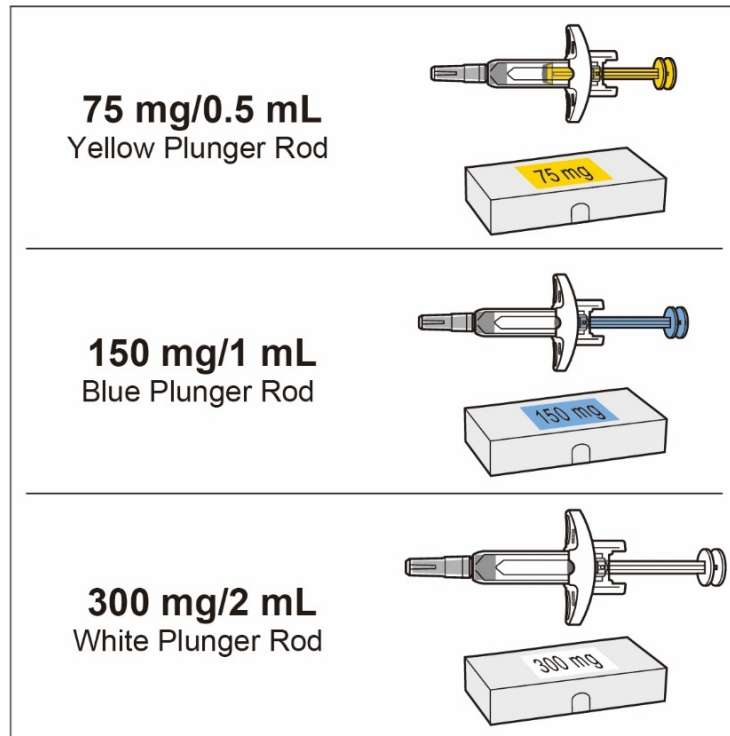


Figure B

Your prescribed dose may require more than 1 injection. The **Dosing Table (Figure C)** below shows the combination of Pre-filled Syringes needed to give your full dose. Check the label on the Omyclo carton to make sure you have received the correct Pre-filled Syringe or combination of Pre-filled 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.

Important

If the dose is for a child under age 12, it is recommended to use only yellow (75 mg) and blue (150 mg) Pre-filled Syringes. Refer to the **Dosing Table (Figure C)** below for the recommended combination of Pre-filled Syringes for children under age 12. Contact your healthcare provider if you have any questions on the **Dosing Table**.

Dosing Table





















| Dose (mg) | Pre-filled Syringes recommended for dose | Yellow (75 mg) | Blue (150 mg) | White (300 mg) |
|-----------------------------|--|---|---|---|
| 75 | 1 yellow |  | | |
| 150 | 1 blue | |  | |
| 225 | 1 yellow + 1 blue |  |  | |
| 300 (ages 12 and up) | 1 white | | |  |
| 300 (children under age 12) | 2 blue | |  | |
| 375 (ages 12 and up) | 1 yellow + 1 white |  | |  |
| 375 (children under age 12) | 1 yellow + 2 blue |  |  | |
| 450 (ages 12 and up) | 1 blue + 1 white | |  |  |
| 450 (children under age 12) | 3 blue | |  | |
| 525 (ages 12 and up) | 1 yellow + 1 blue + 1 white |  |  |  |
| 525 (children under age 12) | 1 yellow + 3 blue |  |  | |
| 600 (ages 12 and up) | 2 white | | |  |
| 600 (children under age 12) | 4 blue | |  | |

Figure C

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

How Should I Store Omlyclo?

- Store the unused Pre-filled Syringes in the original carton in a refrigerator between 2°C to 8°C.
- **Do not** remove the Pre-filled Syringe from its original carton during storage.

- Keep the Pre-filled Syringe in the original carton until ready to use in order to protect from light.
- **Do not** freeze.
- **Do not** use if the Pre-filled 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 Pre-filled Syringe is exposed to temperatures above 25°C, **do not** use it and throw away in a sharps disposal container.
- **Keep the Pre-filled Syringe, sharps disposal container and all medicines out of sight and reach of children. Pre-filled Syringe contains small parts.**

Important Information

- Omlyclo is for subcutaneous injection only (inject directly into fatty layer under the skin).
- The Pre-filled Syringe has a Safety Guard that will be activated to cover the Needle after the injection is finished. The Safety Guard will help to prevent needlestick injuries to anyone who handles the Pre-filled Syringe after injection.
- **Do not** open the sealed carton until you are ready to inject the Pre-filled Syringe.
- **Do not** use if the carton or the Pre-filled Syringe is damaged or appears to be tampered with.
- **Do not** take the Cap off until you are ready to inject the Pre-filled Syringe.
- **Do not** use if the Pre-filled Syringe has been dropped on a hard surface or dropped after removing the Cap.
- **Do not** reuse the same Pre-filled Syringe.
- **Do not** leave the Pre-filled Syringe unattended.
- **Do not** try to take the Pre-filled Syringe apart at any time.
- **Do not** pull back on the Plunger Rod.

Preparing for the Injection

1. Take the carton containing the Pre-filled Syringe out of the refrigerator.

- a. If you need more than 1 Pre-filled 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 Pre-filled Syringe). The following steps must be followed for each Pre-filled Syringe.

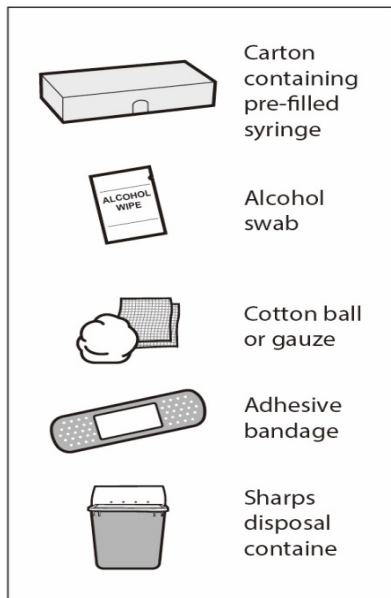


Figure D

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

- Carton containing Pre-filled Syringe
- **Not included in the carton:**
 - Alcohol swab
 - Cotton ball or gauze
 - Adhesive bandage
 - Sharps disposal container

Note: You may need more than 1 Pre-filled Syringe for your prescribed dose. See the **Dosing Table** for more information. Each carton contains 1 Pre-filled Syringe.

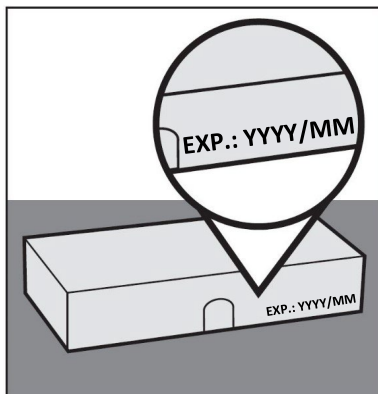


Figure E

3. Check the expiration date 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 sharps disposal container (see **Step 17. Dispose of the Pre-filled Syringe**) and contact your healthcare provider.

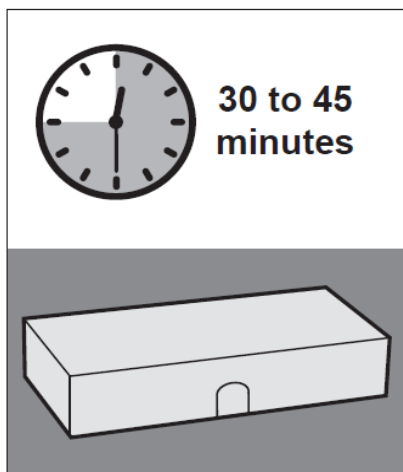


Figure F

4. Allow the Pre-filled Syringe to reach room temperature.

a. 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 Pre-filled Syringe in the carton to protect it from light (see **Figure F**).

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

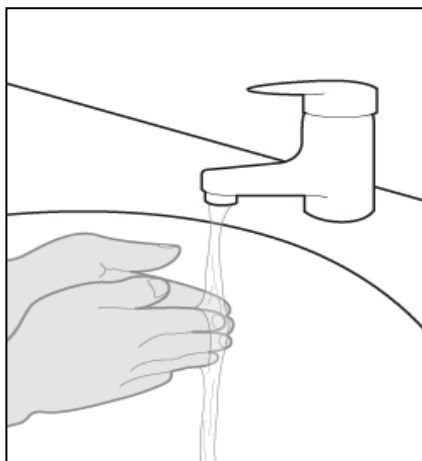


Figure G

5. Wash your hands.

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

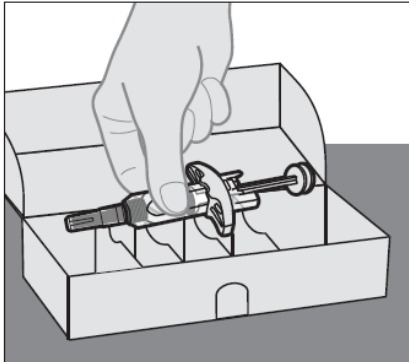


Figure H

6. Remove the Pre-filled Syringe from the carton

- a. Open the carton.
- b. Gripping from the syringe body lift the Pre-filled Syringe from the carton (see **Figure H**)
 - **Do not** touch the Plunger Rod or Cap when removing the Pre-filled Syringe from carton.

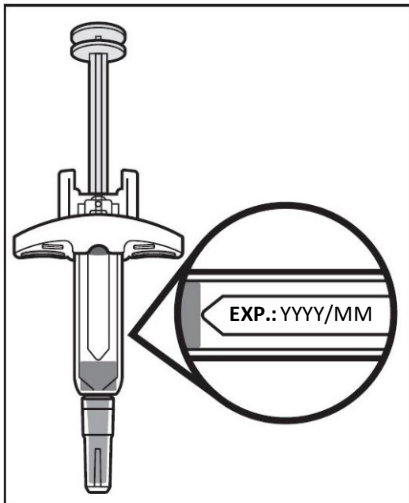


Figure I

7. Inspect the Pre-filled Syringe.

- a. Look at the Pre-filled Syringe and make sure you have the correct Medicine (Omlyclo) and dosage.
- b. Look at the Pre-filled Syringe and make sure it is not cracked or damaged.
 - **Do not** use if the Pre-filled Syringe is damaged or appears to be tampered with.
- c. Check the expiration date on the label of the Pre-filled 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, you may rotate the inner barrel of the Pre-filled Syringe until the expiration date becomes visible.

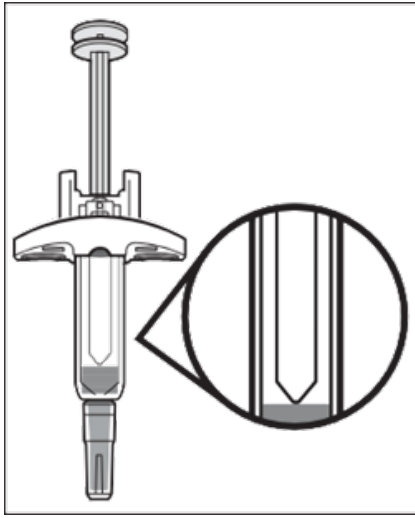


Figure J

8. Inspect the Medicine.

- a. Look at the Medicine and confirm that the liquid is clear to slightly cloudy, colourless to pale brownish-yellow, and free of particles (see **Figure J**).
 - **Do not** use the Pre-filled Syringe if the liquid is discoloured, 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.
- b. If the Medicine does not look as described or if the expiration date has passed, safely dispose of the Pre-filled Syringe in a sharps disposal container (see **Step 17**) and contact your healthcare provider.

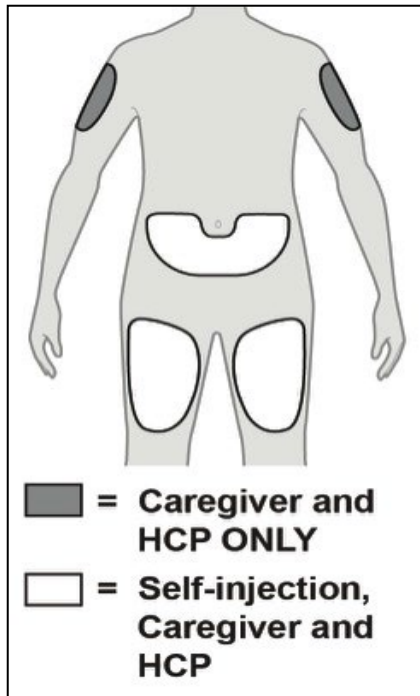


Figure K

9. Choose an injection site (see Figure K)

- a. If you are giving yourself the injection, you can inject into:
 - The front of the thighs.
 - The lower stomach area (lower abdomen) except within the 5 cm area around your belly button (navel).
 - b. If a caregiver or healthcare provider (HCP) is giving the injection, they can use:
 - The outer area of the upper arm.
 - The front of the thighs.
 - The lower stomach area (lower abdomen) except within the 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.
 - If your prescribed dose requires more than 1 injection, make sure your injections are at least 2 cm apart from each other.

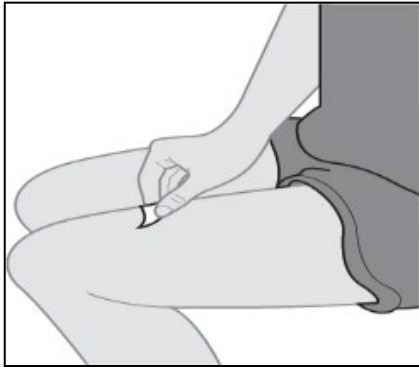


Figure L

10. Clean the injection site.

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

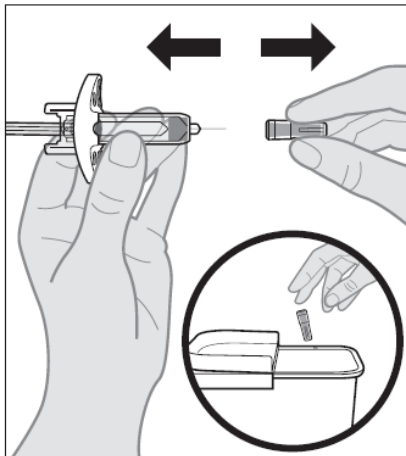


Figure M

11. Remove the Cap.

- a. Hold the Pre-filled Syringe by the syringe body in one hand.
- b. 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.
- c. Dispose of the Cap right away in a sharps disposal container (see **Step 17. Dispose of the Pre-filled Syringe and Figure M**).
 - **Do not** re-cap the Pre-filled Syringe.
 - **Do not** touch the needle or let it touch any surfaces after removing the Cap.

12. Insert the Pre-filled Syringe into the injection site.

- a. 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).

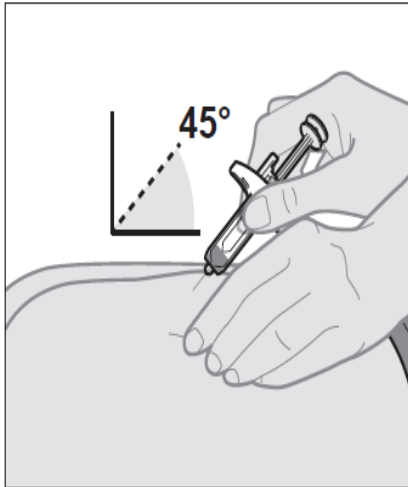


Figure N

- b. 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.
- Once the Needle is inserted, hold the Pre-filled Syringe tightly in place and **do not** change the angle of injection or insert the needle again. The patient should not move and should avoid sudden movements throughout the injection

13. Give the injection.

- a. Slowly push the Plunger Rod **all the way down** until the full dose of medicine gets injected, and the Pre-filled Syringe is empty (see **Figure O**).
- **Do not** change the position of the Pre-filled 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.

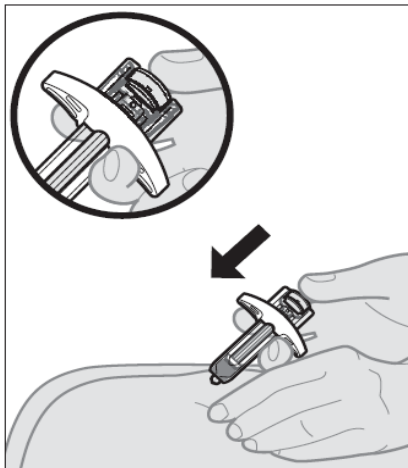


Figure O

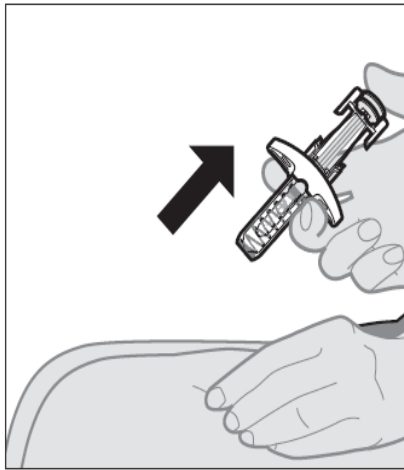


Figure P

14. Remove the Pre-filled Syringe from the injection site.

- a. After the Pre-filled 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 Pre-filled Syringe from the skin and dispose of the Pre-filled Syringe in a sharps disposal container (see **Step 17. Dispose of the Pre-filled Syringe**).
- b. Remove the Pre-filled 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 Pre-filled Syringe.

15. Care for the injection site.

- a. 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.
- b. 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:

- a. Throw away the used Pre-filled Syringe as described in **Step 17. Dispose of the Pre-filled Syringe**.
- b. Repeat **Step 2** through **Step 15** for the next injection using a new Pre-filled Syringe.
 - Make sure each injection is **at least 2 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 Pre-filled Syringe.**

- a. Put the used Pre-filled Syringe in a sharps disposal container right away after use (see **Figure Q**).
 - The Omlyclo Pre-filled Syringe is a single-dose syringe and should not be used again.
 - **Do not** try to put the needle cap back onto the Pre-filled Syringe.
 - **Do not** throw away (dispose of) the Pre-filled Syringe in your household trash.
 - If you do not have a sharps disposal container, you may use a household container that is closable and puncture resistant.
 - Talk to your doctor or pharmacist about proper disposal of the sharps disposal container. There may be local regulations for disposal.

INSTRUCTIONS FOR USE OF 75 mg OMLYCLO PRE-FILLED PEN

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

Adolescents 12 years of age and older: Omlyclo pre-filled pen may be self-administered under adult supervision. The Omlyclo pre-filled pen (all doses) are intended for use only in adults and adolescents aged 12 years and older.

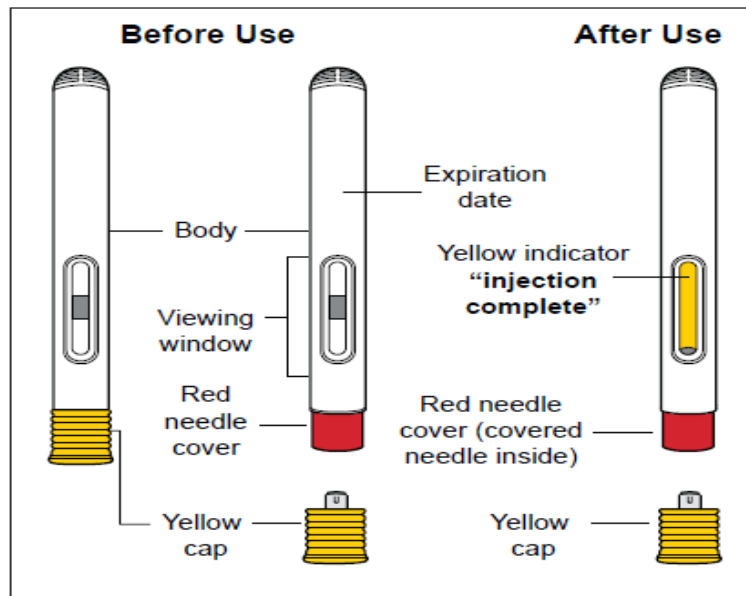


Figure A

Choose the Correct Pre-filled pen or Combination of Pre-filled pens

Omlyclo pre-filled pens are available in 3 dose strengths (see Figure B).

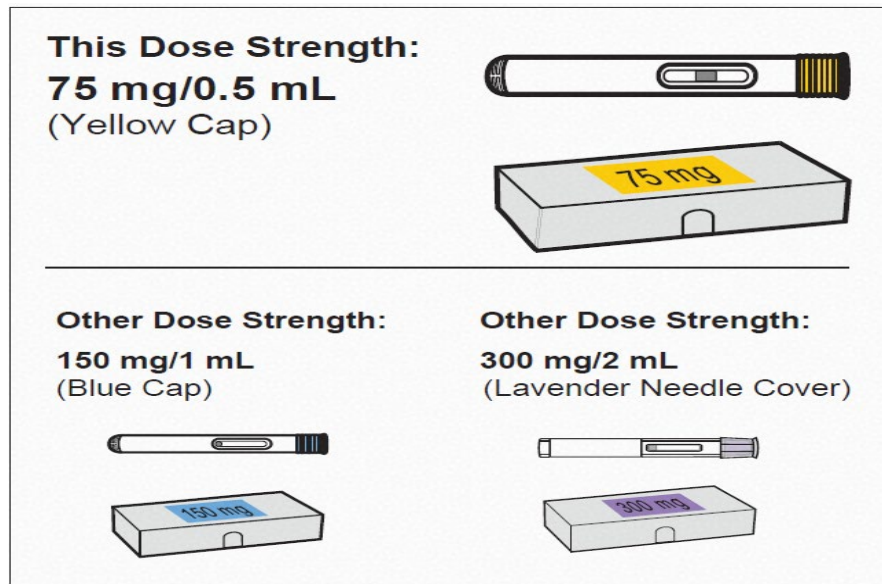


Figure B

Your prescribed dose may require more than 1 injection. The Dosing Table (**Figure C**) below shows the combination of pre-filled pens needed to give your full dose. Check the label on the Omlyclo carton to make sure you have received the correct pre-filled pen or combination of pre-filled pens 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 (mg) | Pre-filled Pens recommended for dose | Yellow (75 mg) | Blue (150 mg) | Lavender (300 mg) |
|-----------|--------------------------------------|----------------|---------------|-------------------|
| 75 | 1 yellow | | | |
| 150 | 1 blue | | | |
| 225 | 1 yellow + 1 blue | | | |
| 300 | 1 lavender | | | |
| 375 | 1 yellow + 1 lavender | | | |
| 450 | 1 blue + 1 lavender | | | |
| 525 | 1 yellow + 1 blue + 1 lavender | | | |
| 600 | 2 lavender | | | |

Figure C

Note: Your healthcare provider may prescribe a different combination of pre-filled pens for your complete dose.

How Should I Store Omlyclo?

- Store the unused pre-filled pen in the original carton in a refrigerator between 2°C to 8°C.
- 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 Omlyclo is exposed to temperatures above 25°C, **do not** use Omlyclo and throw it away in a sharps disposal container.
- **Do not** remove the pre-filled pen from its original carton during storage.
- Keep the pre-filled pen out of direct sunlight.
- **Do not** freeze. **Do not** use if the pre-filled pen has been frozen.
- **Keep the pre-filled pen, sharps disposal container, and all medicines out of sight and the reach of children.**

Important Information

- **Do not** use if the carton is damaged or appears to be tampered with.
- **Do not** open the carton until you are ready to inject.
- **Do not** use the pre-filled pen if it is damaged or appears to be tampered with.
- **Do not** remove the pre-filled pen cap until you are ready to inject Omlyclo.
- **Do not** use if the pre-filled pen has been dropped on a hard surface or dropped after removing the cap.
- **Do not** try to take apart the pre-filled pen at any time.
- **Do not** clean or touch the needle cover.

Preparing for the Injection

1. Take the carton containing the pre-filled pen out of the refrigerator.

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

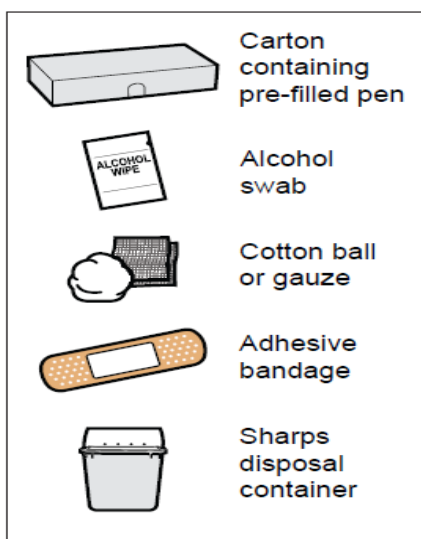


Figure D

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

2.a. Carton containing Omlyclo pre-filled pen

Not included in the carton:

- Alcohol swab
- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container

Note: You may need more than 1 Omlyclo pre-filled pen for your prescribed dose. See the Dosing Table (**Figure C**) for more information. Each Omlyclo carton contains 1 pre-filled pen.

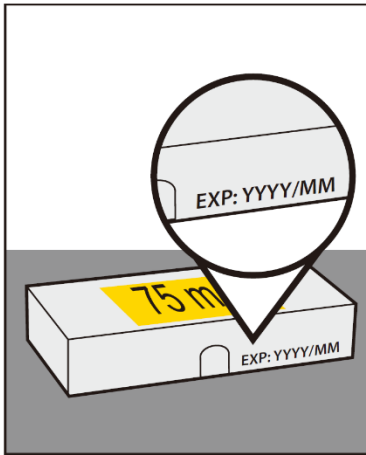


Figure E

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

- **Do not** use the pre-filled pen if the expiration date has passed.
- If the expiration date has passed, throw away the pre-filled pen in a sharps disposal container (see **Step 17**) and contact your healthcare provider.

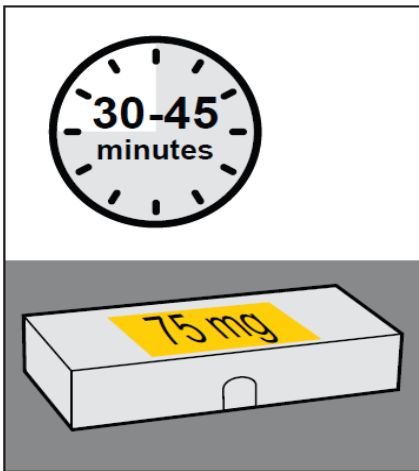


Figure F

4. Allow the pre-filled pen to reach room temperature.

4a. Set aside the carton on a clean flat surface for 30 to 45 minutes so the pre-filled pen can warm up on its own to room temperature. Leave the pre-filled pen in the carton to protect it from light (see **Figure F**).

- If the pre-filled pen does not reach room temperature, this could cause discomfort.
- **Do not** warm the pre-filled pen using heat sources such as hot water or a microwave.

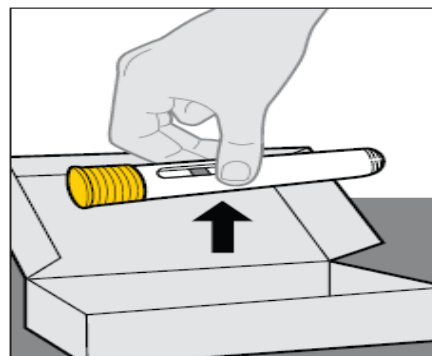


Figure G

5. Open the carton.

5a. Wash your hands with soap and water.
 5b. Take the pre-filled pen out of the carton by holding it from the middle (see **Figure G**).

- **Do not** turn the carton upside down to take out the pre-filled pen as this may damage it.
- **Do not** hold the pre-filled pen by the cap.
- **Do not** remove the cap until you are ready to inject.

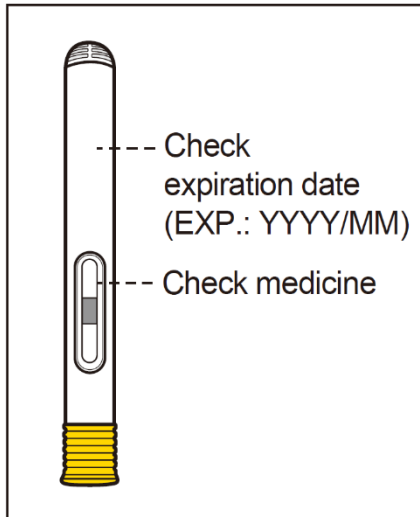


Figure H

6. Check the pre-filled pen

6a. Look through the viewing window of the pre-filled pen to check that the liquid is clear to slightly cloudy, colorless to pale brownish-yellow and free of particles or flakes. You may notice air bubbles in the medicine, which is normal (see **Figure H**).

- **Do not** use the pre-filled pen if the liquid is discolored, distinctly cloudy, or has particles or flakes in it.

6b. Check the expiration date on the pre-filled pen.

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

6c. Check the pre-filled pen for signs of damage or if it appears to be tampered with.

- **Do not** use the pre-filled pen if it appears to be damaged or tampered with.

6d. If the medicine does not look as described or if the expiration date has passed, safely dispose of the pre-filled pen in a sharps disposal container (see **Step 17**) and contact your healthcare provider.

7. Choose an appropriate injection site (see **Figure I**).

7a. The recommended site is:

- The front of the thighs. You may also use the lower abdomen, but **not** the area 5 cm around the navel (belly button).
- The outer area of the upper arm (only if you are a caregiver or healthcare professional (HCP)).

- **Do not** inject into the upper arm by yourself.
- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, or hard, or if there are breaks in the skin.
- **Do not** inject through clothing. The injection site should be exposed, clean skin
- If your prescribed dose requires more than 1 injection, make sure your injections are at least 2 cm apart from each other

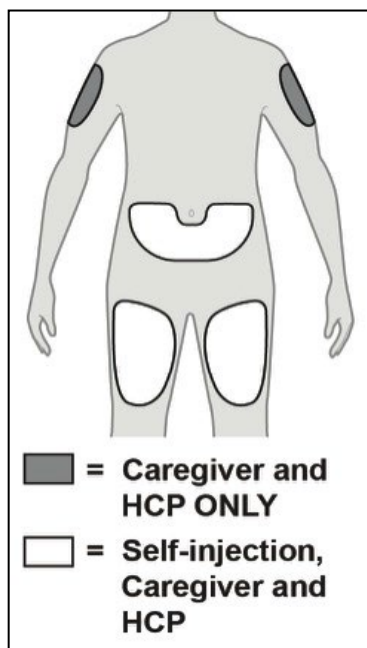


Figure I

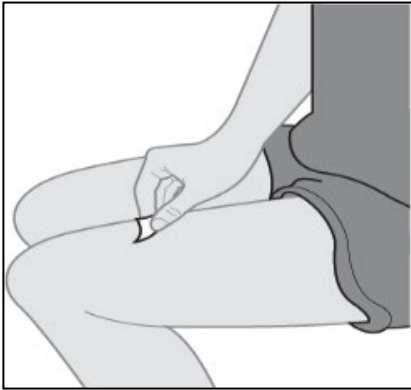


Figure J

8. Clean the injection site.

8a. Wipe the injection site with an alcohol swab in a circular motion and let it air dry for 10 seconds (see **Figure J**).

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

Giving the Injection

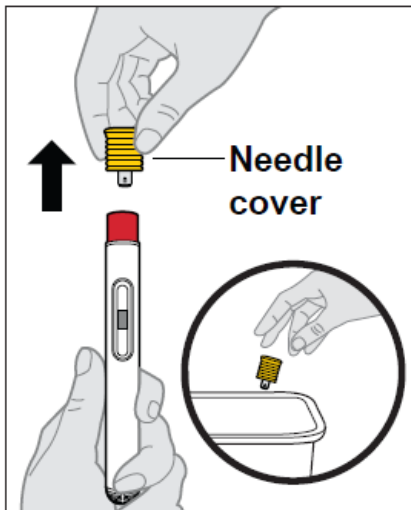


Figure K

9. Remove the cap.

9a. Hold the pre-filled pen firmly with 1 hand and pull the cap straight off with the other hand (see **Figure K**).

- **Do not** twist the cap.
- **Do not** re-cap the pre-filled pen.

9b. Throw away the cap in regular household trash.

- **Do not** clean or touch the needle cover at the tip of the pre-filled pen.

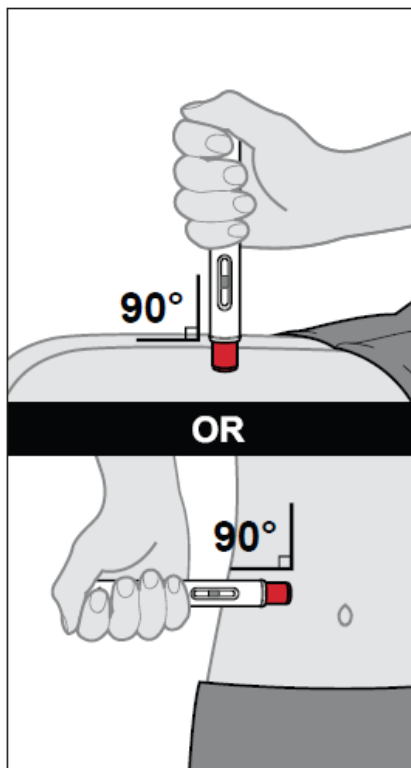


Figure L

10. Position the pre-filled pen.

10a. Hold the pre-filled pen comfortably with the needle cover directly against the skin and position it so you can see the viewing window.

10b. Without pinching or stretching the skin, place the pre-filled pen against the skin at a 90-degree angle (see **Figure L**).

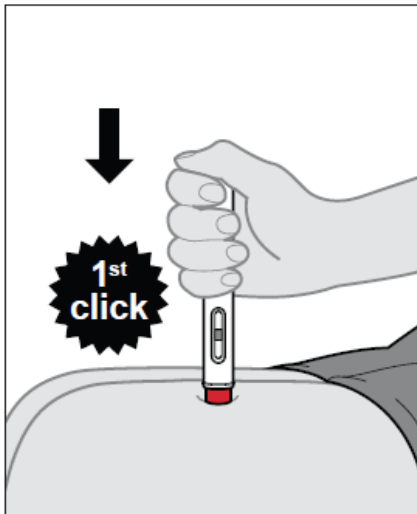


Figure M

11. Start the injection.

11a. Press straight down and hold the pre-filled pen firmly against the skin. The 1st click indicates that the injection has started (see **Figure M**).

11b. Hold the pre-filled pen tightly in place.

- **Do not** change the angle of the injection or remove the pre-filled pen until the injection is completed.

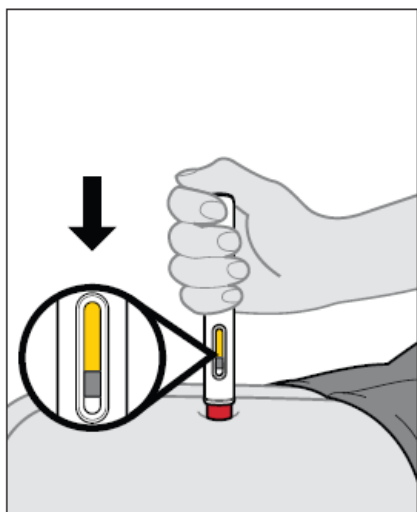


Figure N

12. Monitor the injection using the yellow indicator.

12a. Keep holding the pre-filled pen against the skin. The yellow indicator will move within the viewing window (see **Figure N**).

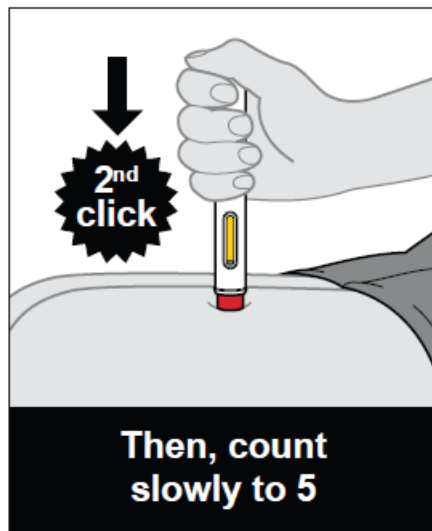


Figure O

13. Complete the injection.

13a. Listen for the 2nd click. This indicates that the injection is almost complete (see **Figure O**).

13b. After you hear the 2nd “click”, continue to hold the pre-filled pen firmly against the skin and **count slowly to 5** to make sure you inject the full dose (see **Figure O**).

13c. Hold the pre-filled pen in position until the yellow indicator has stopped moving and completely fills the viewing window to make sure the injection is complete.

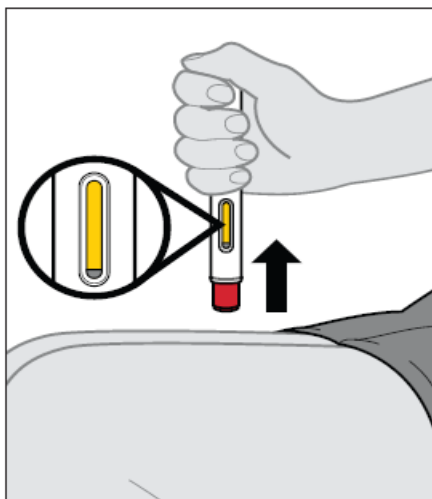


Figure P

14. Remove the pre-filled pen from the skin and check the yellow indicator (see **Figure P**).

14a. After the yellow indicator has stopped moving and has completely filled the viewing window, lift the pre-filled pen straight up from the skin. The needle cover will automatically extend and lock over the needle.

- If the yellow indicator has not completely filled the viewing window, contact your healthcare provider or pharmacist.

15. Care for the injection site.

15a. If a little 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 the case of skin contact with the 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 pre-filled pen as described in **Step 17** and **Figure Q**.

16b. Repeat **Step 2 through Step 15** for the next injection using a new pre-filled pen.

16c. Choose a different injection site for each new injection **at least 2 cm** from other injection sites.

16d. 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**17. Throw away (dispose of) pre-filled pen**

17a. Put the used pre-filled pen and other supplies in a sharps disposal container right away after use (see **Figure Q**).



Figure Q

- **Do not** re-use the pre-filled pen.
- **Do not** re-cap the pre-filled pen.
- **Do not** dispose of your used sharps disposal container in your household trash unless you community guidelines permit this.
- **Do not** recycle your used sharps disposal container.

If you do not have a 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 stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

Talk to your doctor or pharmacist about proper disposal of the sharps disposal container. There may be local regulations for disposal.

INSTRUCTIONS FOR USE OF 150 mg OMLYCLO PRE-FILLED PEN

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

Adolescents 12 years of age and older: Omlyclo pre-filled pen may be self-administered under adult supervision. The Omlyclo pre-filled pen (all doses) are intended for use only in adults and adolescents aged 12 years and older.

Pre-filled pen Parts (see Figure A)

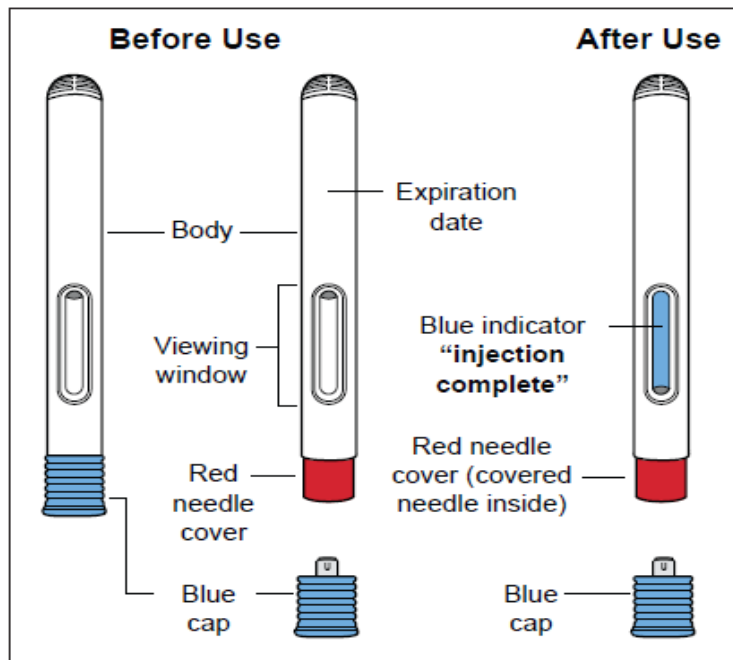


Figure A

Choose the Correct Pre-filled pen or Combination of Pre-filled pens

Omlyclo pre-filled pens are available in 3 dose strengths (see Figure B).

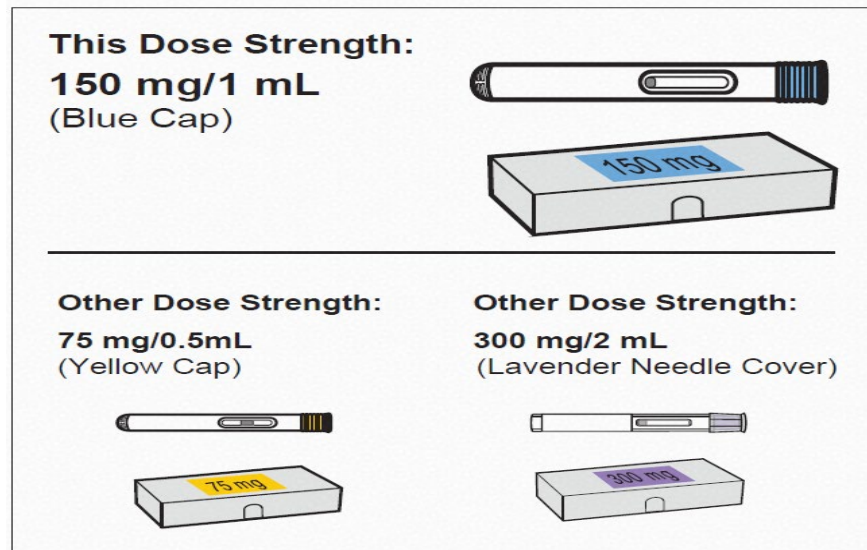


Figure B

Your prescribed dose may require more than 1 injection. The Dosing Table (Figure C) below shows the combination of pre-filled pens needed to give your full dose. Check the label on the Omlyclo carton to make sure you have received the correct pre-filled pen or combination of pre-filled pens 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 (mg) | Pre-filled Pens recommended for dose | Yellow (75 mg) | Blue (150 mg) | Lavender (300 mg) |
|-----------|--------------------------------------|----------------|---------------|-------------------|
| 75 | 1 yellow | | | |
| 150 | 1 blue | | | |
| 225 | 1 yellow + 1 blue | | | |
| 300 | 1 lavender | | | |
| 375 | 1 yellow + 1 lavender | | | |
| 450 | 1 blue + 1 lavender | | | |
| 525 | 1 yellow + 1 blue + 1 lavender | | | |
| 600 | 2 lavender | | | |

Figure C

Note: Your healthcare provider may prescribe a different combination of pre-filled pens for your complete dose.

How Should I Store Omlyclo?

- Store the unused pre-filled pen in the original carton in a refrigerator between 2°C to 8°C.
- 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 Omlyclo is exposed to temperatures above 25°C, **do not** use Omlyclo and throw it away in a sharps disposal container.
- **Do not** remove the pre-filled pen from its original carton during storage.
- Keep the pre-filled pen out of direct sunlight.
- **Do not** freeze. **Do not** use if the pre-filled pen has been frozen.
- **Keep the pre-filled pen, sharps disposal container, and all medicines out of sight and the reach of children.**

Important Information

- **Do not** use if the carton is damaged or appears to be tampered with.
- **Do not** open the carton until you are ready to inject.
- **Do not** use the pre-filled pen if it is damaged or appears to be tampered with.
- **Do not** remove the pre-filled pen cap until you are ready to inject Omlyclo.
- **Do not** use if the pre-filled pen has been dropped on a hard surface or dropped after removing the cap.
- **Do not** try to take apart the pre-filled pen at any time.
- **Do not** clean or touch the needle cover.

Preparing for the Injection

1. Take the carton containing the pre-filled pen out of the refrigerator.

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

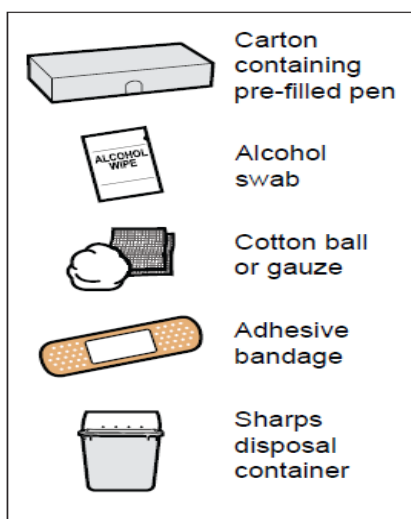


Figure D

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

- 2.a. Carton containing Omlyclo pre-filled pen

Not included in the carton:

- Alcohol swab
- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container

Note: You may need more than 1 Omlyclo pre-filled pen for your prescribed dose. See the Dosing Table (**Figure C**) for more information. Each Omlyclo carton contains 1 pre-filled pen.

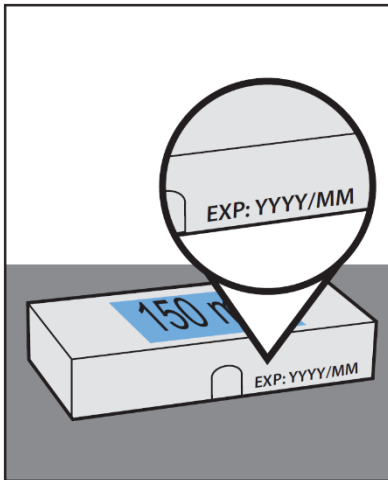


Figure E

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

- **Do not** use the pre-filled pen if the expiration date has passed.
- If the expiration date has passed, throw away the pre-filled pen in a sharps disposal container (see **Step 17**) and contact your healthcare provider.

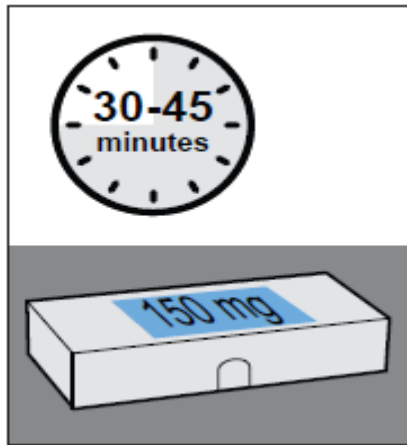


Figure F

4. Allow the pre-filled pen to reach room temperature.

4a. Set aside the carton on a clean flat surface for 30 to 45 minutes so the pre-filled pen can warm up on its own to room temperature. Leave the pre-filled pen in the carton to protect it from light (see **Figure F**).

- If the pre-filled pen does not reach room temperature, this could cause discomfort.
- **Do not** warm the pre-filled pen using heat sources such as hot water or a microwave.

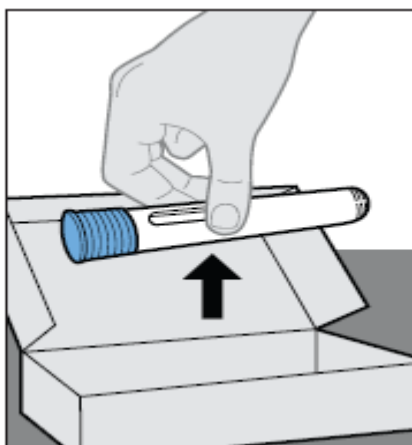


Figure G

5. Open the carton.

5a. Wash your hands with soap and water.
 5b. Take the pre-filled pen out of the carton by holding it from the middle (see **Figure G**).

- **Do not** turn the carton upside down to take out the pre-filled pen as this may damage it.
- **Do not** hold the pre-filled pen by the cap.
- **Do not** remove the cap until you are ready to inject.

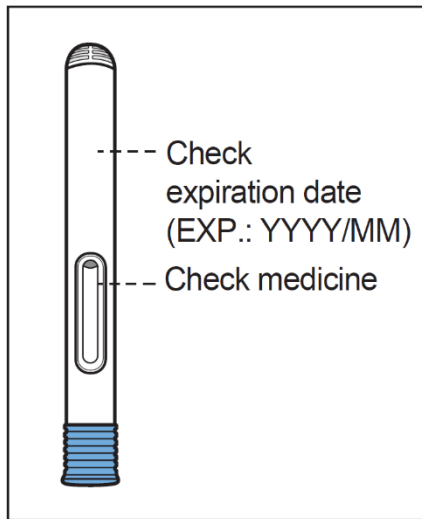


Figure H

6. Check the pre-filled pen

6a. Look through the viewing window of the pre-filled pen to check that the liquid is clear to slightly cloudy, colorless to pale brownish-yellow, and free of particles or flakes. You may notice air bubbles in the medicine, which is normal (see **Figure H**).

- **Do not** use the pre-filled pen if the liquid is discolored, distinctly cloudy, or has particles or flakes in it.

6b. Check the expiration date on the pre-filled pen.

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

6c. Check the pre-filled pen for signs of damage or if it appears to be tampered with.

- **Do not** use the pre-filled pen if it appears to be damaged or tampered with.

6d. If the medicine does not look as described or if the expiration date has passed, safely dispose of the pre-filled pen in a sharps disposal container (see **Step 17**) and contact your healthcare provider.

7. Choose an appropriate injection site (see **Figure I**).

7a. The recommended site is:

- The front of the thighs. You may also use the lower abdomen, but **not** the area 5 cm around the navel (belly button).
- The outer area of the upper arm (only if you are a caregiver or healthcare professional (HCP)).

- **Do not** inject into the upper arm by yourself.
- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, or hard, or if there are breaks in the skin.
- **Do not** inject through clothing. The injection site should be exposed, clean skin.
- If your prescribed dose requires more than 1 injection, make sure your injections are at least 2 cm apart from each other.

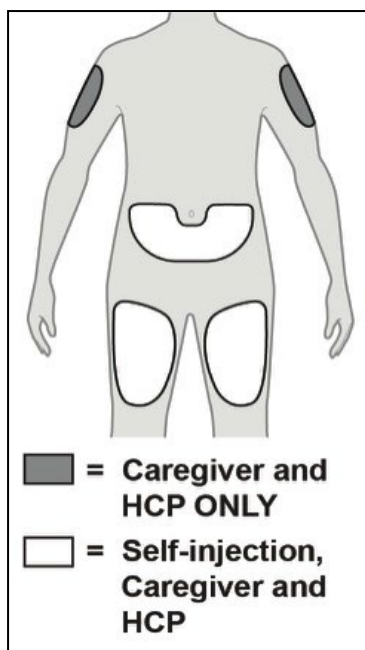


Figure I

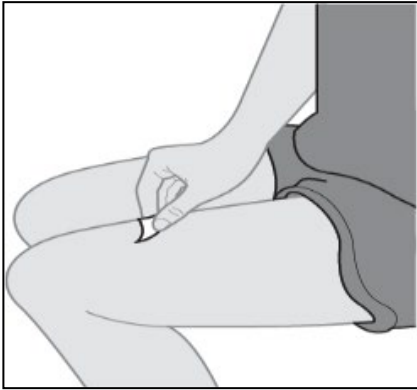


Figure J

8. Clean the injection site.

8a. Wipe the injection site with an alcohol swab in a circular motion and let it air dry for 10 seconds (see **Figure J**).

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

Giving the Injection

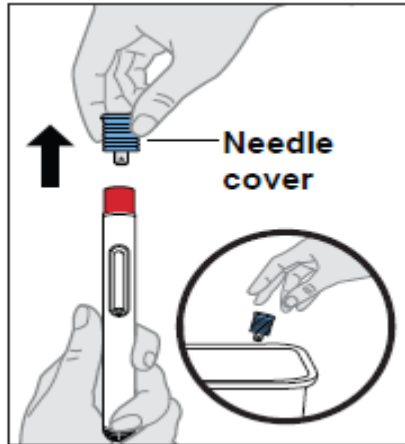


Figure K

9. Remove the cap.

9a. Hold the pre-filled pen firmly with 1 hand and pull the cap straight off with the other hand (see **Figure K**).

- **Do not** twist the cap.
- **Do not** re-cap the pre-filled pen.

9b. Throw away the cap in regular household trash.

- **Do not** clean or touch the needle cover at the tip of the pre-filled pen.

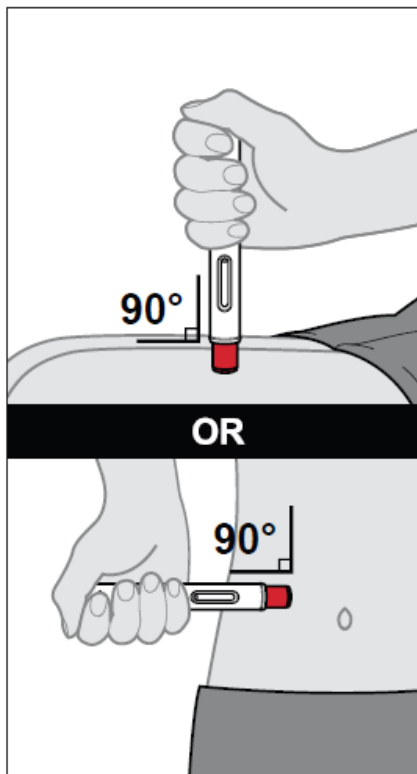


Figure L

10. Position the pre-filled pen.

10a. Hold the pre-filled pen comfortably with the needle cover directly against the skin and position it so you can see the viewing window.

10b. Without pinching or stretching the skin, place the pre-filled pen against the skin at a 90-degree angle (see **Figure L**).

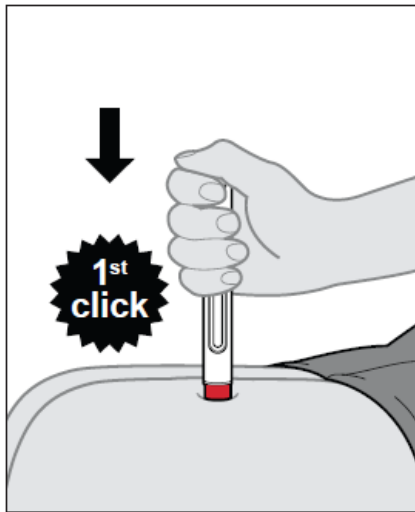


Figure M

11. Start the injection.

11a. Press straight down and hold the pre-filled pen firmly against the skin. The 1st click indicates that the injection has started (see **Figure M**).

11b. Hold the pre-filled pen tightly in place.

- **Do not** change the angle of the injection or remove the pre-filled pen until the injection is completed.

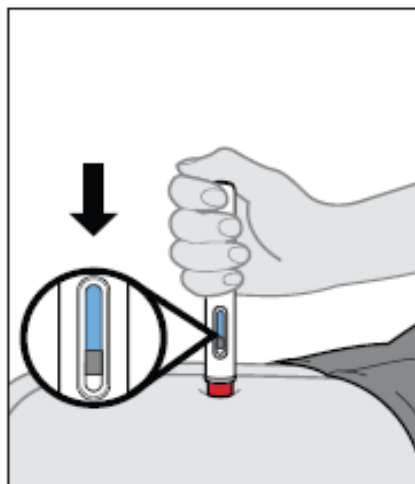


Figure N

12. Monitor the injection using the blue indicator.

12a. Keep holding the pre-filled pen against the skin. The blue indicator will move within the viewing window (see **Figure N**).

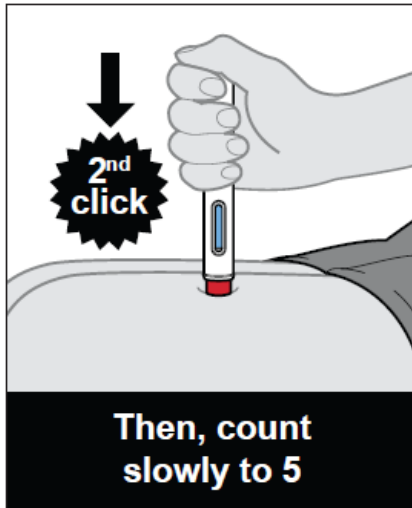


Figure O

13. Complete the injection.

13a. Listen for the 2nd click. This indicates that the injection is almost complete (see **Figure O**).

13b. After you hear the 2nd “click”, continue to hold the pre-filled pen firmly against the skin and **count slowly to 5** to make sure you inject the full dose (see **Figure O**).

13c. Hold the pre-filled pen in position until the blue indicator has stopped moving and completely fills the viewing window to make sure the injection is complete.

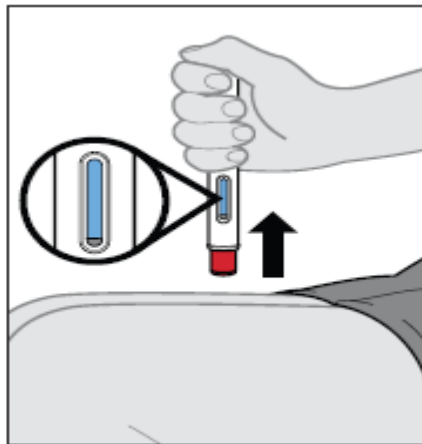


Figure P

14. Remove the pre-filled pen from the skin and check the blue indicator (see Figure P).

14a. After the blue indicator has stopped moving and has completely filled the viewing window, lift the pre-filled pen straight up from the skin. The needle cover will automatically extend and lock over the needle.

- If the blue indicator has not completely filled the viewing window, contact your healthcare provider or pharmacist.

15. Care for the injection site.

15a. If a little 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 the case of skin contact with the 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 pre-filled pen as described in **Step 17** and **Figure Q**.

16b. Repeat **Step 2 through Step 15** for the next injection using a new pre-filled pen.

16c. Choose a different injection site for each new injection **at least 2 cm** from other injection sites.

16d. 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**17. Throw away (dispose of) pre-filled pen.**

17a. Put the used pre-filled pen and other supplies in a sharps disposal container right away after use (see **Figure Q**).



Figure Q

- **Do not** re-use the pre-filled pen.
- **Do not** re-cap the pre-filled pen.
- **Do not** dispose of your used sharps disposal container in your household trash unless you community guidelines permit this.
- **Do not** recycle your used sharps disposal container.

If you do not have a 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 stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

Talk to your doctor or pharmacist about proper disposal of the sharps disposal container. There may be local regulations for disposal.

INSTRUCTIONS FOR USE OF 300 mg OMLYCLO PRE-FILLED PEN

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

Adolescents 12 years of age and older: Omlyclo pre-filled pen may be self-administered under adult supervision. The Omlyclo pre-filled pen (all doses) are intended for use only in adults and adolescents aged 12 years and older.

Pre-filled pen Parts (see Figure A)

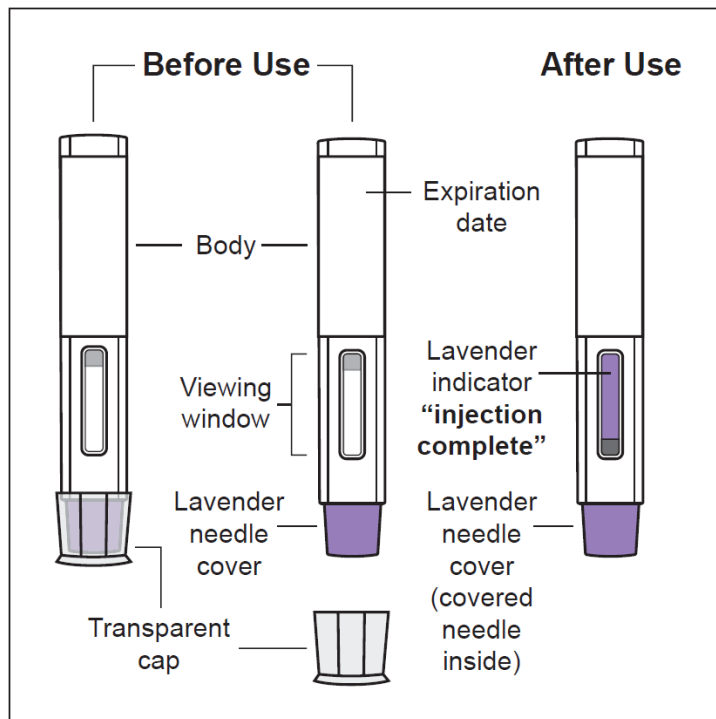


Figure A

Choose the Correct Pre-filled pen or Combination of Pre-filled pens

Omyclo pre-filled pens are available in 3 dose strengths (see **Figure B**).

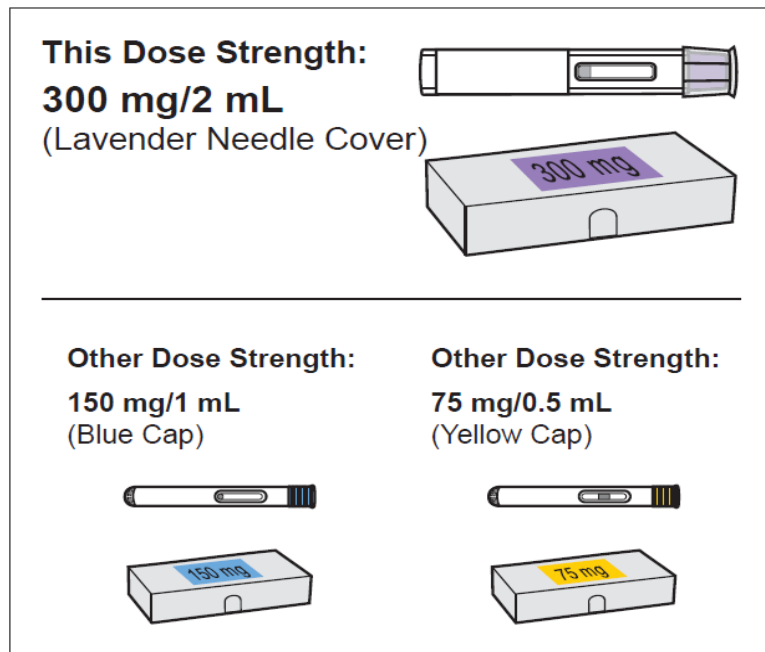


Figure B

Your prescribed dose may require more than 1 injection. The Dosing Table (**Figure C**) below shows the combination of pre-filled pens needed to give your full dose. Check the label on the Omyclo carton to make sure you have received the correct pre-filled pen or combination of pre-filled pens 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 (mg) | Pre-filled Pens recommended for dose | Yellow (75 mg) | Blue (150 mg) | Lavender (300 mg) |
|-----------|--------------------------------------|---|---|---|
| 75 | 1 yellow |  | | |
| 150 | 1 blue | |  | |
| 225 | 1 yellow + 1 blue |  |  | |
| 300 | 1 lavender | | |  |
| 375 | 1 yellow + 1 lavender |  | |  |
| 450 | 1 blue + 1 lavender | |  |  |
| 525 | 1 yellow + 1 blue + 1 lavender |  |  |  |
| 600 | 2 lavender | | |  |

Figure C

Note: Your healthcare provider may prescribe a different combination of pre-filled pens for your complete dose.

How Should I Store Omlyclo?

- Store the unused pre-filled pen in the original carton in a refrigerator between 2°C to 8°C.
- 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 Omlyclo is exposed to temperatures above 25°C, **do not** use Omlyclo and throw it away in a sharps disposal container.
- **Do not** remove the pre-filled pen from its original carton during storage.
- Keep the pre-filled pen out of direct sunlight.
- **Do not** freeze. **Do not** use if the pre-filled pen has been frozen.
- **Keep the pre-filled pen, sharps disposal container, and all medicines out of sight and the reach of children. Contains small parts.**

Important Information

- Omlyclo is for subcutaneous injection only (inject directly into fatty layer under the skin).
- **Do not** use if the carton is damaged or appears to be tampered with.
- **Do not** open the carton until you are ready to inject.
- **Do not** use the pre-filled pen if it has damaged or appears to be tampered with.
- **Do not** remove the pre-filled pen cap until you are ready to inject Omlyclo.
- **Do not** use if the pre-filled pen has been dropped on a hard surface or dropped after removing the cap.
- **Do not** try to take apart the pre-filled pen at any time.
- **Do not** clean or touch the needle cover.

Preparing for the Injection

1. Take the carton containing the pre-filled pen out of the refrigerator.

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

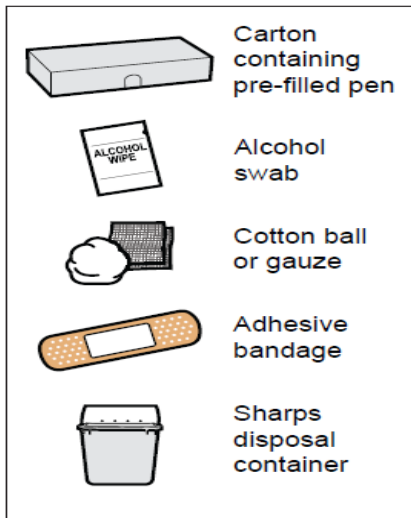


Figure D

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

- Carton containing Omlyclo pre-filled pen

Not included in the carton:

- Alcohol swab
- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container

Note: You may need more than 1 Omlyclo pre-filled pen for your prescribed dose. See the Dosing Table (**Figure C**) for more information. Each Omlyclo carton contains 1 pre-filled pen.

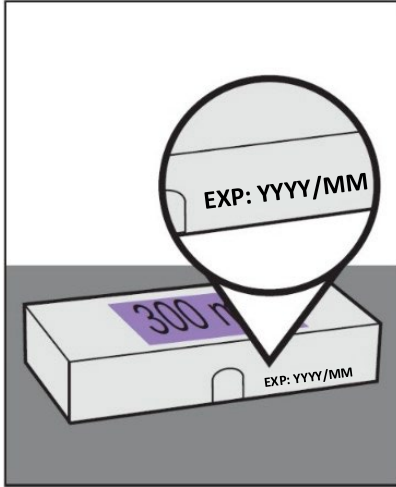


Figure E

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

- **Do not** use the pre-filled pen if the expiration date has passed.
- If the expiration date has passed, throw away the pre-filled pen in a sharps disposal container (see **Step 17**) and contact your healthcare provider.

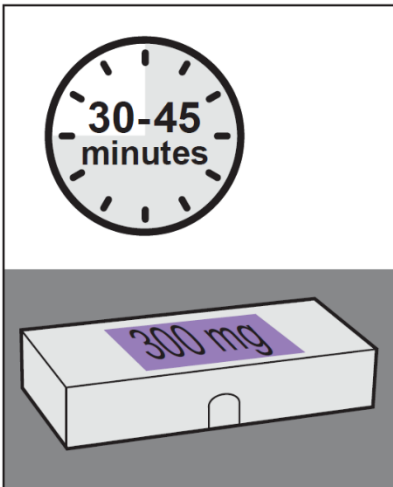


Figure F

4. Allow the pre-filled pen to reach room temperature.

4a. Set aside the carton on a clean flat surface for 30 to 45 minutes so the pre-filled pen can warm up on its own to room temperature. Leave the pre-filled pen in the carton to protect it from light (see **Figure F**).

- If the pre-filled pen does not reach room temperature, this could cause discomfort.
- **Do not** warm the pre-filled pen using heat sources such as hot water or a microwave.

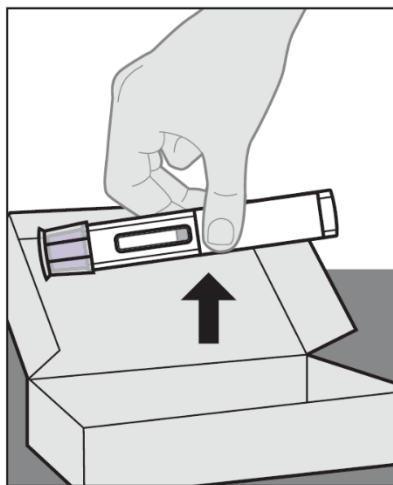


Figure G

5. Open the carton.

5a. Wash your hands with soap and water.
5b. Take the pre-filled pen out of the carton by holding it from the middle (see **Figure G**).

- **Do not** turn the carton upside down to take out the pre-filled pen as this may damage it.
- **Do not** hold the pre-filled pen by the cap.
- **Do not** remove the cap until you are ready to inject.

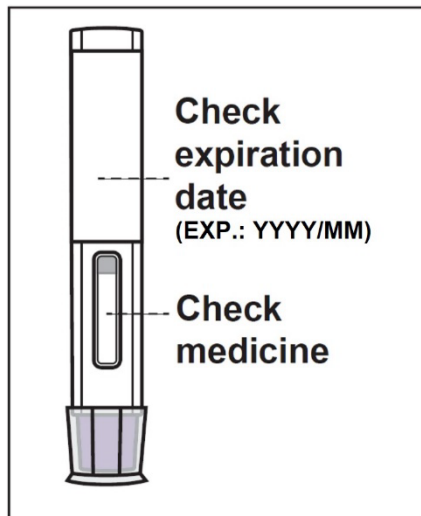


Figure H

6. Check the pre-filled pen before use.

6a. Look through the viewing window of the pre-filled pen to check that the liquid is clear to slightly cloudy, colourless to pale brownish-yellow, and free of particles or flakes. You may notice air bubbles in the medicine, which is normal (see **Figure H**).

- **Do not** use the pre-filled pen if the liquid is discoloured, distinctly cloudy, or has particles or flakes in it.

6b. Check the expiration date on the pre-filled pen.

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

6c. Check the pre-filled pen for signs of damage or if it appears to be tampered with.

- **Do not** use the pre-filled pen if it appears to be damaged or tampered with.

6d. If the medicine does not look as described or if the expiration date has passed, safely dispose of the pre-filled pen in a sharps disposal container (see **Step 17**) and contact your healthcare provider.

7. Choose an appropriate injection site (see **Figure I**).

7a. The recommended site is:

- The front of the thighs. You may also use the lower abdomen, but **not** the area 5 cm around the navel (belly button).
- The outer area of the upper arm (only if you are a caregiver or healthcare professional (HCP)).

- **Do not** inject into the upper arm by yourself.

- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, or hard, or if there are breaks in the skin.

- **Do not** inject through clothing. The injection site should be exposed, clean skin.

- If your prescribed dose requires more than 1 injection, make sure your injections are at least 2 cm apart from each other.

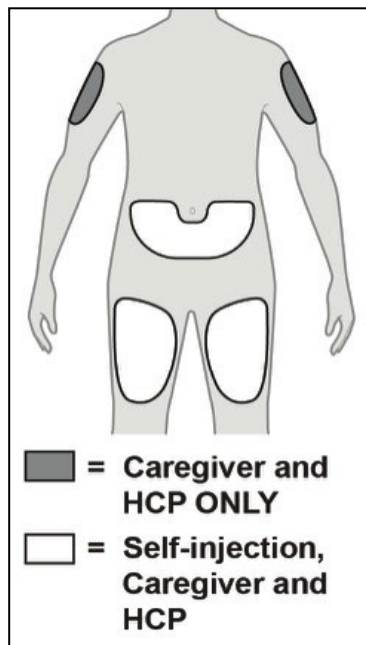


Figure I

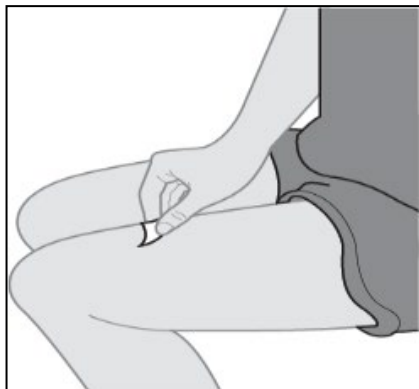


Figure J

8. Clean the injection site.

8a. Wipe the injection site with an alcohol swab in a circular motion and let it air dry for 10 seconds (see **Figure J**).

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

Giving the Injection

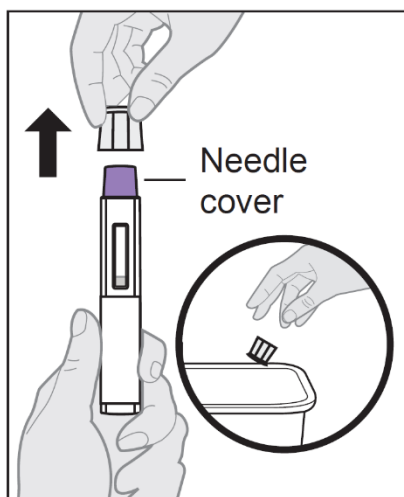


Figure K

9. Remove the cap.

9a. Hold the pre-filled pen firmly with 1 hand and pull the cap straight off with the other hand (see **Figure K**).

- **Do not** twist the cap.
- **Do not** re-cap the pre-filled pen.
 - You may see a few drops of liquid at the tip of the needle. This is normal

9b. Throw away the cap in regular household trash.

- **Do not** clean or touch the needle cover at the tip of the pre-filled pen.

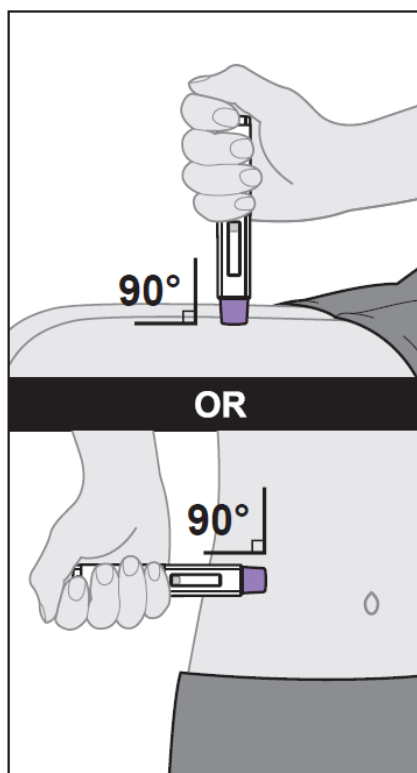


Figure L

10. Position the pre-filled pen.

10a. Hold the pre-filled pen comfortably with the needle cover directly against the skin and position it so you can see the viewing window.

10b. Without pinching or stretching the skin, place the pre-filled pen against the skin at a 90-degree angle (see **Figure L**).

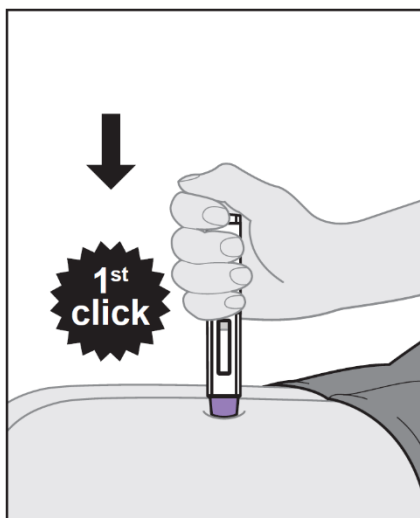


Figure M

11. Start the injection.

11a. Press straight down and hold the pre-filled pen firmly against the skin. The 1st click indicates that the injection has started (see **Figure M**).

11b. Hold the pre-filled pen tightly in place.

- **Do not** change the angle of the injection or remove the pre-filled pen until the injection is completed.

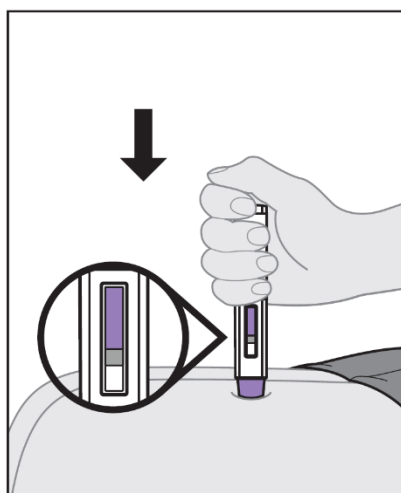


Figure N

12. Monitor the injection using the lavender indicator.

12a. Keep holding the pre-filled pen against the skin. The lavender indicator will move within the viewing window (see **Figure N**).

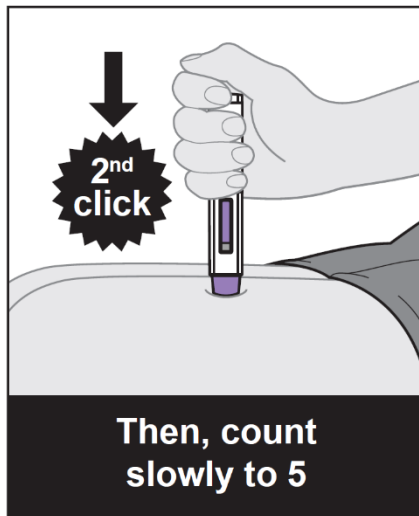


Figure O

13. Complete the injection.

13a. Listen for the 2nd click. This indicates that the injection is almost complete (see **Figure O**).

13b. After you hear the 2nd “click”, continue to hold the pre-filled pen firmly against the skin and **count slowly to 5** to make sure you inject the full dose (see **Figure O**).

13c. Hold the pre-filled pen in position until the lavender indicator has stopped moving and completely fills the viewing window to make sure the injection is complete.

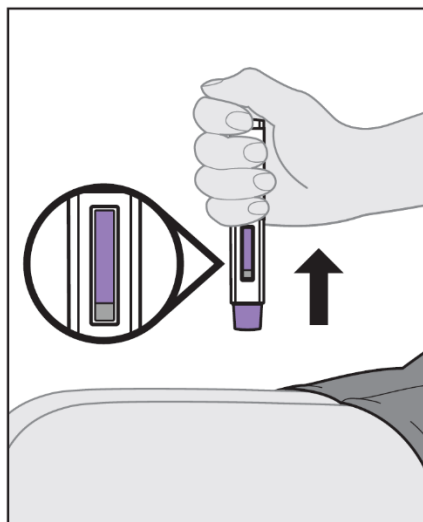


Figure P

14. Remove the pre-filled pen from the skin and check the lavender indicator (see **Figure P**).

14a. After the lavender indicator has stopped moving and has completely filled the viewing window, lift the pre-filled pen straight up from the skin. The needle cover will automatically extend and lock over the needle.

14b. If the lavender indicator has not completely filled the viewing window, contact your healthcare provider or pharmacist.

15. Care for the injection site.

15a. If a little 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 the case of skin contact with the 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 pre-filled pen as described in **Step 17** and **Figure Q**.

16b. Repeat **Step 2 through Step 15** for the next injection using a new pre-filled pen.

16c. Choose a different injection site for each new injection **at least 2 cm** from other injection sites.

16d. 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**17. Throw away (dispose of) pre-filled pen.**

17a. Put the used pre-filled pen and other supplies in a sharps disposal container right away after use (see **Figure Q**).

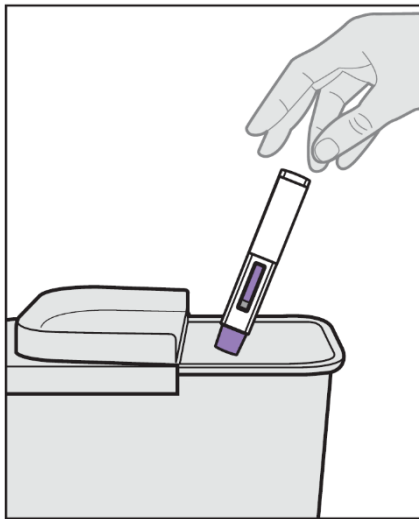


Figure Q

- **Do not** re-use the pre-filled pen.
- **Do not** re-cap the pre-filled pen.
- **Do not** dispose of your used sharps disposal container in your household trash unless you community guidelines permit this.
- **Do not** recycle your used sharps disposal container.

If you do not have a 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 stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

Talk to your doctor or pharmacist about proper disposal of the sharps disposal container. There may be local regulations for disposal.

Usual dose:**Asthma and Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

Omlyclo is given once every 2 or 4 weeks. Your dose will be determined by your body weight and your IgE level, which your doctor will measure with a simple blood test. Based on your dose, your doctor will also tell you if you will need 1, 2, 3 or 4 injections per dose. If you need more than 1 injection, each will be given in a different place on your body.

Because it is a controller or maintenance medicine, you will receive Omlyclo on a regular schedule. It is important that you continue to receive your Omlyclo injections even when you are feeling well.

Chronic Idiopathic Urticaria (CIU)

You will be given 1 or 2 injections at a time every 4 weeks.

Continue taking your current medicine for CIU during Omlyclo treatment. Do not stop taking any medicine without talking to your doctor first.

Continue to use Omlyclo for as long as your doctor tells you to do so.

If you have questions about how long to receive Omlyclo, talk to your doctor or your pharmacist.

Overdose:

The maximum tolerated dose of Omlyclo has not been determined. Single intravenous doses up to 4000 mg have been administered to patients without evidence of dose-limiting toxicities. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

If you think you, or a person you are caring for, have taken too much Omlyclo, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you have missed an appointment to get an Omlyclo injection, contact your doctor and get it as soon as you remember.

If you have forgotten a dose of Omlyclo, inject the dose as soon as you remember. Then talk to your doctor to discuss when to inject the next dose.

Possible side effects from using Omlyclo:

These are not all the possible side effects you may have when taking Omlyclo. If you experience any side effects not listed here, tell your healthcare professional.

As with all medicines, patients treated with omalizumab can experience side effects.

The side effects caused by omalizumab are usually mild. In clinical studies, they were about as common in people who were given omalizumab as those who were given a placebo (or dummy) injection that did not contain omalizumab.

Look out for signs of allergic reactions and other serious side effects:

Omalizumab can potentially cause serious side effects. You must look out for signs of these conditions while you use omalizumab. Some patients had a serious allergic reaction called anaphylaxis, occurring at an average of 2 out of 1000 patients (0.2%) or more. Should it happen, anaphylaxis quickly causes symptoms such as rash, itching, and swelling of the tongue and throat, which can make it hard to breathe and can be life threatening. Seek medical help immediately if you notice any signs indicating a severe allergic reaction or other serious side effects. Such signs are in the “**Serious side effects and what to do about them**” table. Please speak with your doctor about this information.

It is important that you receive training from your healthcare professional in how to recognize early signs of severe allergic reactions, and how to manage these reactions if they occur (see **How to take Omlyclo** section). The majority of severe allergic reactions occur within the first 3 doses of omalizumab.

Take special care if you have a disorder where your own immune system attacks part of your own body (autoimmune disease).

A specific type of allergic reaction (serum sickness) has also been observed in patients treated with omalizumab or similar products. Signs include joint pain, stiffness, rash, fever, swollen/enlarged lymph nodes and occur typically within one to five days after the injection. If you have such a reaction after taking omalizumab, contact a doctor immediately.

In initial clinical studies in asthma, the number of observed malignancies was uncommon (<1%) in all studied patients who received omalizumab or a placebo injection containing no medication, with 0.5% reported in patients receiving omalizumab and 0.2% in patients receiving placebo injections. Results from a review of all the clinical trials now completed (double in size from the initial studies) and also results from a 5 year observational study found that omalizumab was not associated with an increased risk of malignancy. Please discuss this information with your doctor.

The most common side effects reported in patients who received omalizumab in clinical studies in asthma, CRSwNP and CIU are listed below. These are not all the possible side effects you may have when taking omalizumab. If you experience any side effects not listed here, tell your healthcare professional.

- Injection-site reaction (bruising, redness, warmth, burning, stinging, or other discomfort around the injection site)
- Viral infections
- Upper respiratory tract infection
- Sinusitis
- Headache
- Sore throat
- Urinary tract infection
- Feeling dizzy
- Abdominal pain

In children 6 to less than 12 years of age with asthma:

- Common cold symptoms
- Headache
- Fever
- Sore throat

- Pain or discomfort of your ear
- Nausea
- Vomiting
- Nose bleeding

Other less commonly observed side effects included pain, broken bones, leg pain, joint pain, muscle pain, joint swelling, and hair loss.

If you notice hives, skin rash, injection site reactions or any side effects not mentioned in this leaflet, please inform your doctor or nurse.

If you experience any of these, tell your doctor straight away.

| Serious side effects and what to do about them | | | |
|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| RARE | | | |
| Sudden severe allergic reaction (e.g.anaphylaxis): sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, fast heartbeat, dizziness and light headedness, shortness of breath, wheezing or trouble Breathing | | | ✓ |
| Low blood platelet count with symptoms such as bleeding or bruising more easily than normal | | | ✓ |
| Churg-Strauss syndrome: Joint appearance of some of the following symptoms: Pain, numbness or tingling in the arms and legs, lumps or raised patches in the skin, weakness and fatigue, loss of appetite and weight loss | | | ✓ |
| Serum-sickness: Joint appearance of some of the following symptoms: Joint pain, stiffness, rash, fever, swollen/enlarged lymph nodes. When it occurs this is usually between one to five days after injection | | | ✓ |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough

to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Omyclo is to be stored in a refrigerator (2 to 8°C). Do not freeze. In order to protect from light, store in the original package. Any unused product or waste material should be disposed of in accordance with local requirements. Your doctor or nurse will know this. Do not shake.

Keep out of reach and sight of children.

If you want more information about Omyclo:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.celltrionhealthcare.ca/.)

This leaflet was prepared by Celltrion, Inc.

Last Revised : TBD