

## Package leaflet: Information for the user

### **Omlyclo 150 mg solution for injection in pre-filled syringe** **Omlyclo 300 mg solution for injection in pre-filled syringe** omalizumab

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Omlyclo is and what it is used for
2. What you need to know before you use Omlyclo
3. How to use Omlyclo
4. Possible side effects
5. How to store Omlyclo
6. Contents of the pack and other information

#### **1. What Omlyclo is and what it is used for**

Omlyclo contains the active substance omalizumab. Omalizumab is a man-made protein that is similar to natural proteins produced by the body. It belongs to a class of medicines called monoclonal antibodies.

Omlyclo is used for the treatment of:

- allergic asthma
- chronic rhinosinusitis (inflammation of the nose and sinuses) with nasal polyps
- chronic spontaneous urticaria (CSU)

##### Allergic asthma

This medicine is used to prevent asthma from getting worse by controlling symptoms of severe allergic asthma in adults, adolescents and children (6 years of age and older) who are already receiving asthma medicine, but whose asthma symptoms are not well controlled by medicines such as high-dose steroid inhalers and beta-agonist inhalers.

##### Chronic rhinosinusitis with nasal polyps

This medicine is used to treat chronic rhinosinusitis with nasal polyps in adults (18 years of age and older) who are already receiving intranasal corticosteroids (corticosteroid nasal spray), but whose symptoms are not well controlled by these medicines. Nasal polyps are small growths on the lining of the nose. Omlyclo helps to reduce the size of the polyps and improves symptoms including nasal congestion, loss of sense of smell, mucus in the back of the throat and runny nose.

##### Chronic spontaneous urticaria (CSU)

This medicine is used to treat chronic spontaneous urticaria in adults and adolescents (12 years of age and older) who are already receiving antihistamines but whose CSU symptoms are not well controlled by these medicines.

Omlyclo works by blocking a substance called immunoglobulin E (IgE), which is produced by the body. IgE contributes to a type of inflammation that plays a key role in causing allergic asthma, chronic rhinosinusitis with nasal polyps and CSU.

## **2. What you need to know before you use Omlyclo**

### **Do not use Omlyclo:**

- if you are allergic to omalizumab or any of the other ingredients of this medicine (listed in section 6). (See special warnings at the end of this section under subtitle “Omlyclo contains polysorbate”)
- if you think you may be allergic to any of the ingredients, tell your doctor as you should not use Omlyclo.

### **Warnings and precautions**

Talk to your doctor before using Omlyclo:

- if you have kidney or liver problems.
- if you have a disorder where your own immune system attacks parts of your own body (autoimmune disease).
- if you are travelling to region where infections caused by parasites are common – Omlyclo may weaken your resistance to such infections.
- if you have had a previous severe allergic reaction (anaphylaxis), for example resulting from a medicine, an insect bite or food.

Omlyclo does not treat acute asthma symptoms, such as a sudden asthma attack. Therefore, Omlyclo should not be used to treat such symptoms.

Omlyclo is not meant to prevent or treat other allergy-type conditions, such as sudden allergic reactions, hyperimmunoglobulin E syndrome (an inherited immune disorder), aspergillosis (a fungus-related lung disease), food allergy, eczema or hay fever because Omlyclo has not been studied in these conditions.

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

Omlyclo can potentially cause serious side effects. You must look out for signs of these conditions while you use Omlyclo. Seek medical help immediately if you notice any signs indicating a severe allergic reaction or other serious side effects. Such signs are listed under “Serious side effects” in section 4.

It is important that you receive training from your doctor in how to recognise early symptoms of severe allergic reactions, and how to manage these reactions if they occur, before you inject Omlyclo yourself or before a non-healthcare professional gives you a Omlyclo injection (see section 3, “How to use Omlyclo”). The majority of severe allergic reactions occur within the first 3 doses of Omlyclo.

### **Children and adolescents**

#### Allergic asthma

Omlyclo is not recommended for children under 6 years of age. Its use in children under 6 years of age has not been studied.

#### Chronic rhinosinusitis with nasal polyps

Omlyclo is not recommended for children and adolescents under 18 years of age. Its use in patients under 18 years of age has not been studied.

#### Chronic spontaneous urticaria (CSU)

Omlyclo is not recommended for children under 12 years of age. Its use in children under 12 years of age has not been studied.

### **Other medicines and Omlyclo**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking:

- medicines to treat an infection caused by a parasite, as Omlyclo may reduce the effect of your medicines,
- inhaled corticosteroids and other medicines for allergic asthma.

### **Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Your doctor will discuss with you the benefits and potential risks of using this medicine during pregnancy.

If you become pregnant while being treated with Omlyclo, tell your doctor immediately.

Omlyclo may pass into breast milk. If you are breast-feeding or plan to breast-feed, ask your doctor for advice before using this medicine.

### **Driving and using machines**

It is unlikely that Omlyclo will affect your ability to drive and use machines.

### **Omlyclo contains polysorbate**

Each Omlyclo 150 mg pre-filled syringe contains 0.40 mg of polysorbate 20 and each Omlyclo 300 mg pre-filled syringe contains 0.80 mg of polysorbate 20, which is equivalent to 0.40 mg/ml. Polysorbates may cause allergic reactions. Tell your doctor if you or your child has any known allergies.

## **3. How to use Omlyclo**

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure

### **How Omlyclo is used**

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

#### Injecting Omlyclo

- You and your doctor will decide if you should inject Omlyclo yourself. The first 3 doses are always given by or under the supervision of a healthcare professional (see section 2).
- 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” at the end of this leaflet.

#### Training to recognise serious allergic reactions

It is also important that you do not inject Omlyclo yourself until you have been trained by your doctor or nurse on:

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

For more information about the early signs and symptoms of serious allergic reactions, see section 4.

## **How much to use**

### Allergic asthma and chronic rhinosinusitis with nasal polyps

Your doctor will decide how much Omlyclo you need and how often you will need it. This depends on your body weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in your blood.

You will need 1 to 4 injections at a time. You will need the injections either every two weeks, or every four weeks.

Keep taking your current asthma and/or nasal polyps medicine during Omlyclo treatment. Do not stop taking any asthma and/or nasal polyps medicine without talking to your doctor.

You may not see an immediate improvement after beginning Omlyclo treatment. In patients with nasal polyps effects have been seen 4 weeks after the start of the treatment. In asthma patients it usually takes between 12 and 16 weeks to have the full effect.

### Chronic spontaneous urticaria (CSU)

You will need two 150 mg injections at a time or one 300 mg injection every four weeks.

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

## **Use in children and adolescents**

### Allergic asthma

Omlyclo can be used in children and adolescents aged 6 years and older, who are already receiving asthma medicine, but whose asthma symptoms are not well controlled by medicines such as high dose steroid inhalers and beta-agonist inhalers. Your doctor will work out how much Omlyclo your child needs and how often it needs to be given. This will depend on your child's weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in his/her blood.

Children (6 to 11 years of age) should not self-administer Omlyclo. However, if considered appropriate by their doctor, a caregiver may give them their Omlyclo injection after proper training.

Omlyclo 300 mg pre-filled syringe is 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 6-11 years of age with allergic asthma.

### Chronic rhinosinusitis with nasal polyps

Omlyclo should not be used in children and adolescents under 18 years of age.

### Chronic spontaneous urticaria (CSU)

Omlyclo can be used in adolescents aged 12 years of age and older, who are already receiving antihistamines but whose CSU symptoms are not well controlled by these medicines. The dose for adolescents aged 12 years and above is the same as for adults.

## **If you use more Omlyclo than you should**

If you have used or been given too much Omlyclo, talk to a doctor or pharmacist straight away. Always have the outer carton of the medicine with you, even if it is empty.

## **If a dose of Omlyclo is missed**

If you have missed an appointment, contact your doctor or hospital as soon as possible to re-schedule it.

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

### **If you stop treatment with Omlyclo**

Do not stop treatment with Omlyclo unless your doctor tells you to. Interrupting or stopping the treatment with Omlyclo may cause your symptoms to come back.

However, if you are being treated for CSU, your doctor may stop Omlyclo treatment from time to time so that your symptoms can be assessed. Follow your doctor's instructions.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects caused by Omlyclo are usually mild to moderate but can occasionally be serious.

### Serious side effects:

Seek medical attention immediately if you notice any signs of the following side effects:

Rare (may affect up to 1 in 1000 people)

- Severe allergic reactions (including anaphylaxis). Symptoms may include rash, itching or hives on the skin, swelling of the face, lips, tongue, larynx (voice box), windpipe or other parts of the body, fast heartbeat, dizziness and light-headedness, confusion, shortness of breath, wheezing or trouble breathing, blue skin or lips, collapsing and losing consciousness. If you have a history of severe allergic reactions (anaphylaxis) unrelated to Omlyclo you may be more at risk of developing a severe allergic reaction following use of Omlyclo.
- Systemic lupus erythematosus (SLE). Symptoms may include muscle pain, joint pain and swelling, rash, fever, weight loss, and fatigue.

Not known (frequency cannot be estimated from the available data)

- Churg-Strauss syndrome or hypereosinophilic syndrome. Symptoms may include one or more of the following: swelling, pain or rash around blood or lymph vessels, high level of a specific type of white blood cells (marked eosinophilia), worsening problems with breathing, nasal congestion, heart problems, pain, numbness, tingling in the arms and legs.
- Low blood platelet count with symptoms such as bleeding or bruising more easily than normal.
- Serum sickness. Symptoms may include one or more of the following: joint pain with or without swelling or stiffness, rash, fever, swollen lymph nodes, muscle pain.

### Other side effects include:

Very common (may affect more than 1 in 10 people)

- fever (in children)

Common (may affect up to 1 in 10 people)

- reactions at the injection site including pain, swelling, itching and redness
- pain in the upper part of the tummy
- headache (very common in children)
- upper respiratory tract infection, such as inflammation of the pharynx and common cold
- feeling of pressure or pain in the cheeks and forehead (sinusitis, sinus headache)
- pain in joints (arthralgia)
- feeling dizzy

Uncommon (may affect up to 1 in 100 people)

- feeling sleepy or tired
- tingling or numbness of the hands or feet
- fainting, low blood pressure while sitting or standing (postural hypotension), flushing
- sore throat, coughing, acute breathing problems
- feeling sick (nausea), diarrhoea, indigestion
- itching, hives, rash, increased sensitivity of the skin to sun
- weight increase

- flu-like symptoms
- swelling arms

Rare (may affect up to 1 in 1000 people)

- parasitic infection

Not known (frequency cannot be estimated from the available data)

- muscle pain and joint swelling
- hair loss

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Omlyclo**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. The carton containing the pre-filled syringe can be stored for a total time of 7 days at room temperature (25 °C) before use.
- Store in the original package in order to protect from light.
- Store in a refrigerator (2 °C – 8 °C). Do not freeze.
- Do not use any pack that is damaged or shows signs of tampering.

## **6. Contents of the pack and other information**

### **What Omlyclo contains**

- The active substance is omalizumab.
  - One syringe of 1 ml solution contains 150 mg omalizumab.
  - One syringe of 2 ml solution contains 300 mg omalizumab.
- The other ingredients are L-arginine hydrochloride, L-histidine hydrochloride monohydrate, L-histidine, Polysorbate 20 (E 432) and water for injections.

### **What Omlyclo looks like and contents of the pack**

Omlyclo solution for injection is supplied as a clear to slightly cloudy, colourless to pale brownish-yellow solution in a pre-filled syringe.

Omlyclo 150 mg solution for injection is available in a pack containing 1 pre-filled syringe and in multipacks containing 6 (6 x 1) or 10 (10 x 1) pre-filled syringes.

Omlyclo 300 mg solution for injection is available in a pack containing 1 pre-filled syringe and in multipacks containing 2 (2 x 1), 3 (3 x 1) or 6 (6 x 1) pre-filled syringes.

Not all pack sizes may be marketed in your country.

### **Marketing Authorisation Holder**

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## 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)

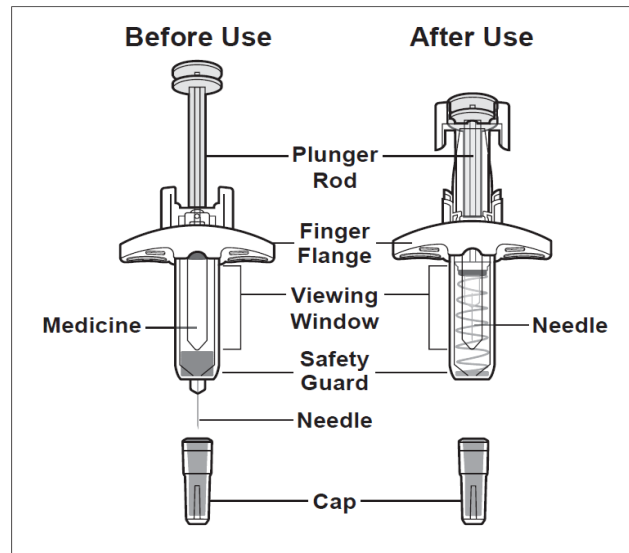


Figure A

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

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

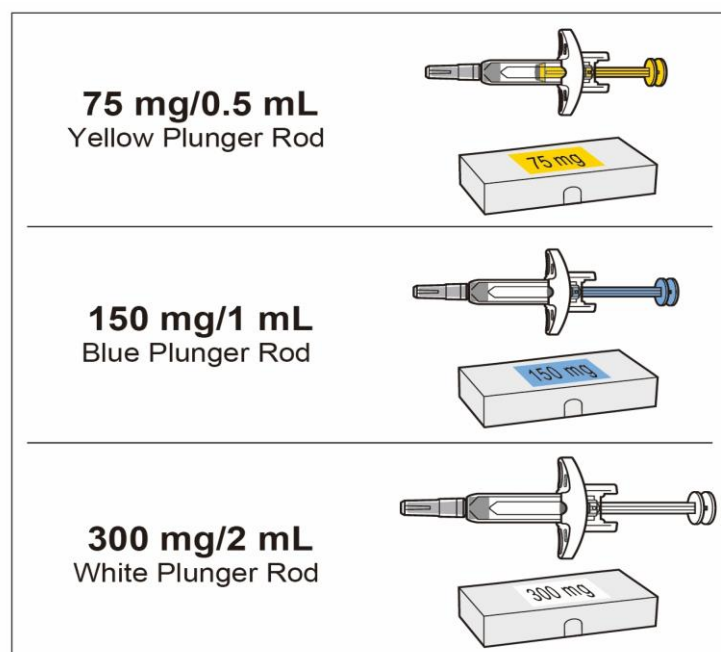





















Figure B

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 Omlyclo 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, since white (300 mg) Pre-filled Syringe is not intended for use in patients under 12 years of age. 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 Needed		
	Yellow (75 mg)	Blue (150 mg)	White (300 mg)
75			
150			
225	 + 		
300 (ages 12 and up)			
300 (children under age 12)			
375 (ages 12 and up)		+	
375 (children under age 12)	 + 		
450 (ages 12 and up)			+
450 (children under age 12)			
525 (ages 12 and up)	 + 	+	
525 (children under age 12)	 + 		
600 (ages 12 and up)			
600 (children under age 12)			

**Figure C**

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

### Important information you need to know before injecting Omlyclo

- 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 use 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.

### How Should I Store Omlyclo?

- Store the unused Pre-filled Syringes in the original carton in a refrigerator between 2 °C and 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.**

### Preparing for the Injection

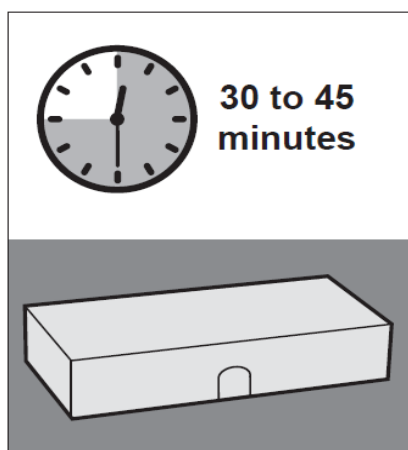


Figure D

#### 1. Take the carton containing the Pre-filled Syringe out of the refrigerator and Allow the Pre-filled Syringe to reach room temperature.

- 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.
- b. 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 D**).
  - **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.

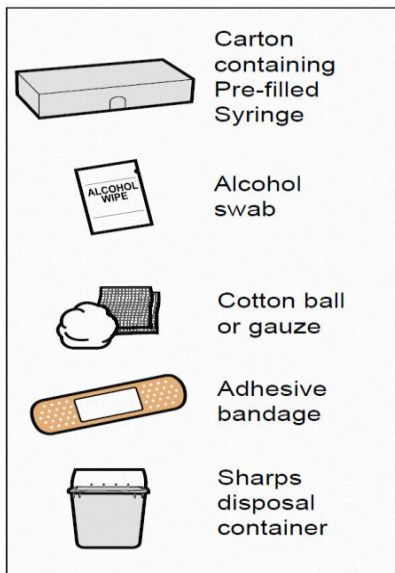


Figure E

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

- 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** (see **Figure C**) for more information. Each carton contains 1 Pre-filled Syringe.

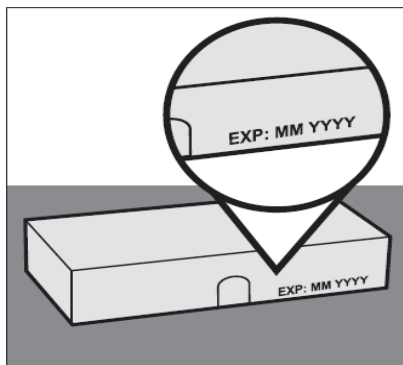


Figure F

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

- **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 16. Dispose of the Pre-filled Syringe**) and contact your healthcare provider.

**4. Wash your hands.**

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

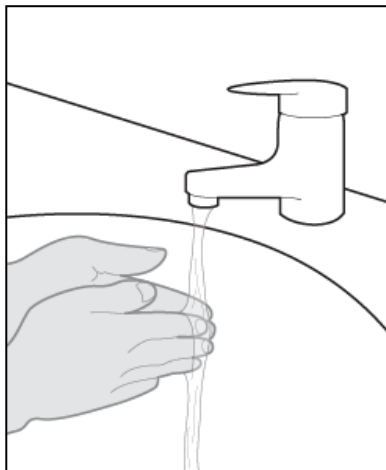
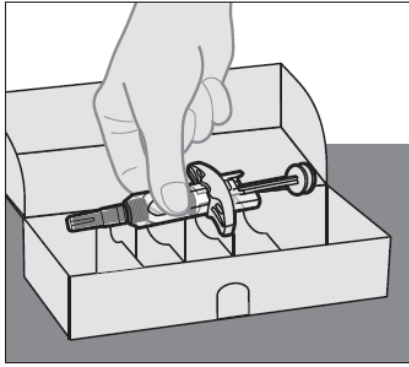


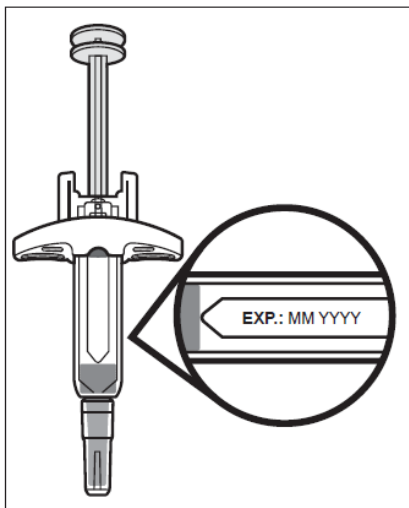
Figure G



**Figure H**

**5. 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

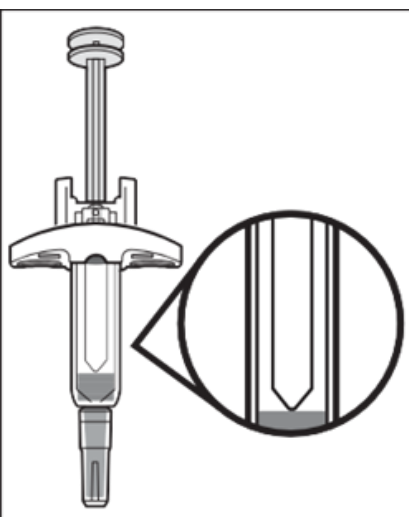


**Figure I**

**6. 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.

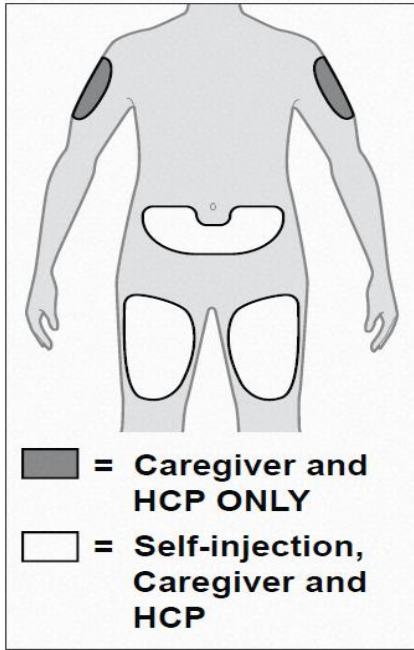
*Note:* If the expiration date is not visible in the viewing window, you may rotate the inner barrel of the Pre-filled Syringe until the expiration date becomes visible.



**Figure J**

**7. Inspect the Medicine.**

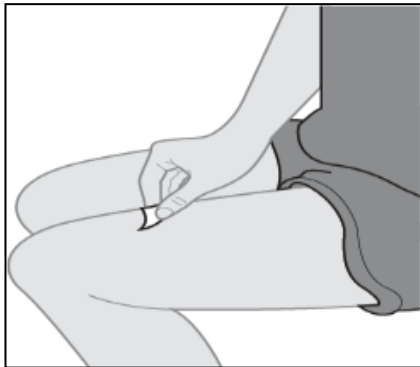
- a. Look at the Medicine and confirm that the liquid is clear to slightly cloudy, colourless to pale brownish-yellow, and free of particles (see **Figure J**).
  - **Do not** use the Pre-filled Syringe if the liquid is discoloured, distinctly cloudy, or contains particles in it.
  - You may see air 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 16**) and contact your healthcare provider.



**Figure K**

**8. 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**

**9. 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 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

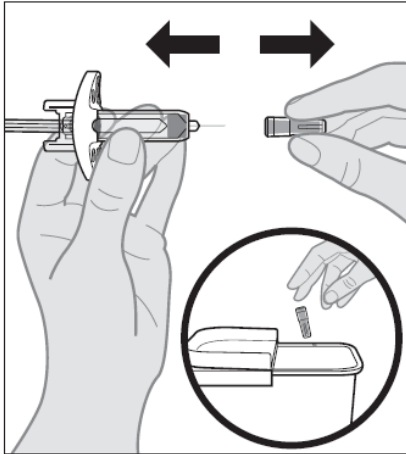


Figure M

### 10. 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 16. 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.

### 11. 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).

- 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

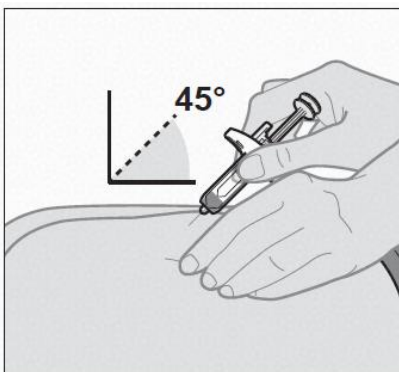


Figure N

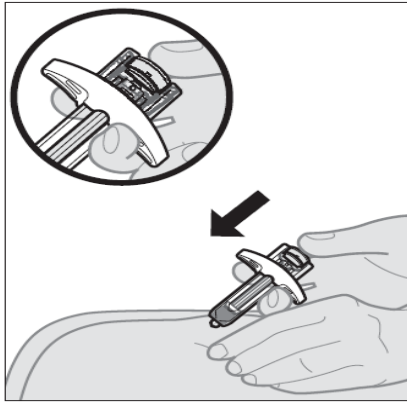


Figure O

## 12. 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.

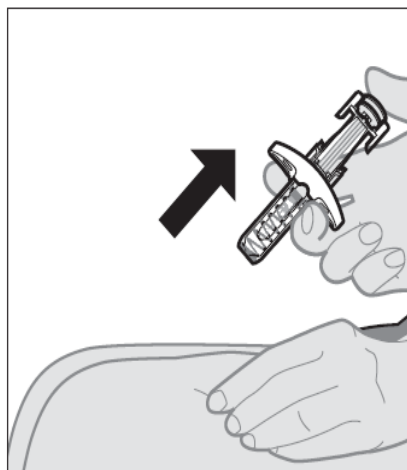


Figure P

## 13. 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 16. 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 14. Care for the injection site**).
  - **Do not** reuse the Pre-filled Syringe.

## 14. 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.

## 15. If your prescribed dose requires more than 1 injection:

- a. Throw away the used Pre-filled Syringe as described in **Step 16. Dispose of the Pre-filled Syringe**.
- b. Repeat **Step 1** through **Step 14** 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**

**16. 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.