

Package leaflet: Information for the user

Omlyclo 300 mg solution for injection in pre-filled pen 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 an 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

This medicine contains 0.80 mg of polysorbate 20 in each pre-filled pen, 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 pen” 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 3 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 one 300 mg injection at a time 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 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 6-11 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 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 pen 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 pen 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 pen.

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

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

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Uxbridge, UB8 1JG,
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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INSTRUCTIONS FOR USE OF OMLYCLO PRE-FILLED PEN

Read and follow the Instructions for Use that come with your 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)

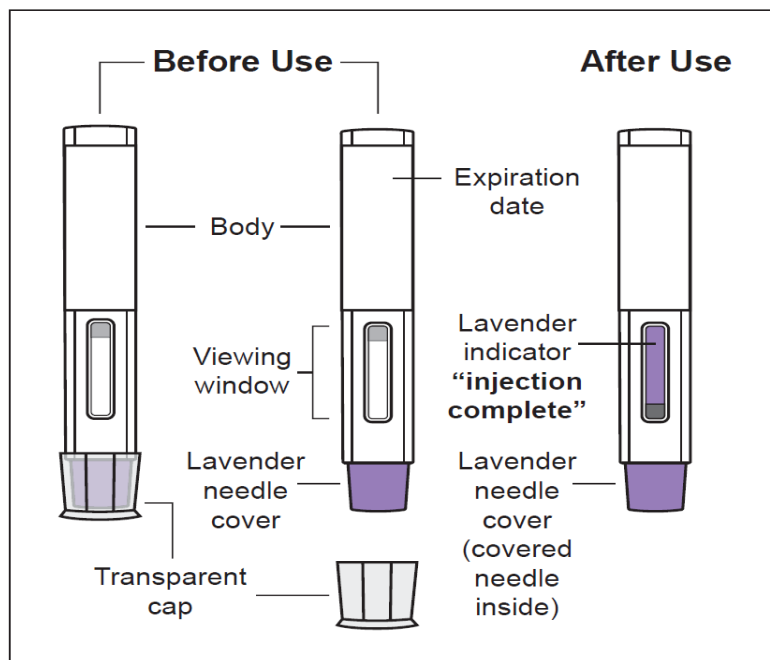


Figure A

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).

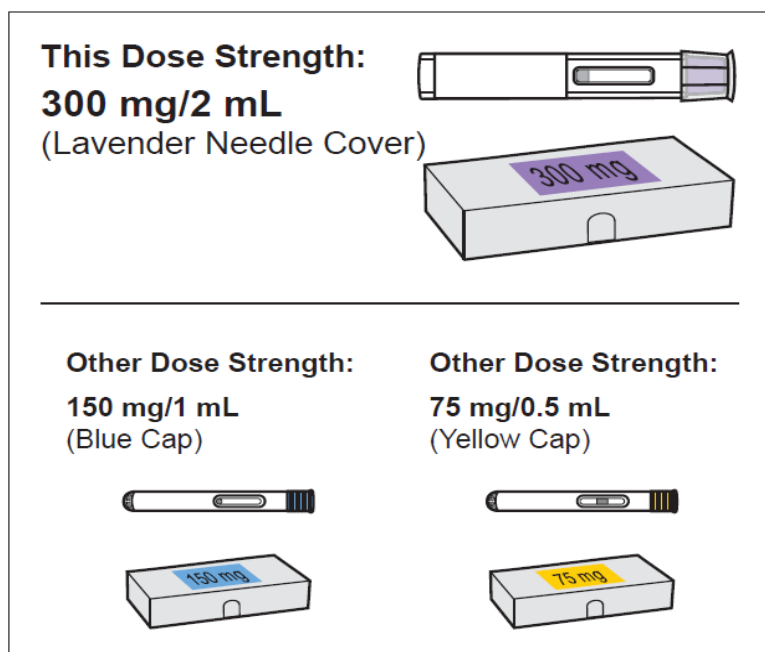


Figure B

Your prescribed dose may require more than 1 injection. The **Dosing Table (Figure C)** to the 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

	Pre-filled Pens Needed		
Dose (mg)	Yellow (75 mg)	Blue (150 mg)	Lavender (300 mg)
75			
150			
225	 + 		
300			
375			+ 
450			+ 
525	 + 		+ 
600			

Figure C

Note: Your healthcare provider may prescribe a different combination of pre-filled pens 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).
- **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 been damaged or appears to be tampered with.
- **Do not** remove the 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.

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.**

Preparing for the Injection

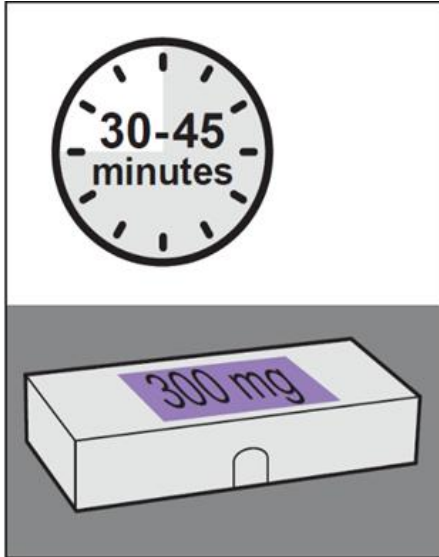


Figure D

1. Take the carton containing the Pre-filled Pen out of the refrigerator and allow the Pre-filled Pen to reach room temperature.

- 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.
- 1.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 pen in the carton to protect it from light (see **Figure D**).
 - **Do not** warm the pre-filled pen using heat sources such as hot water or a microwave.
 - If the pre-filled pen does not reach room temperature, this could cause discomfort.

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

- 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.

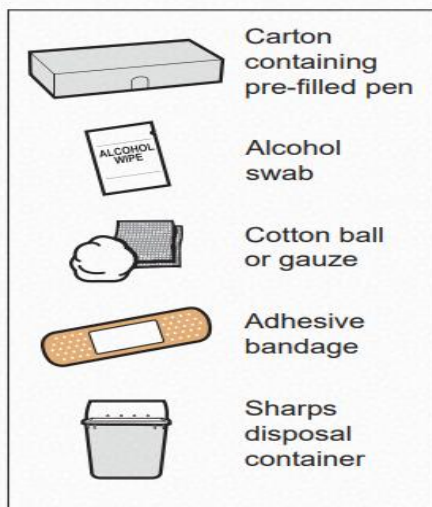


Figure E

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

- **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 16**) and contact your healthcare provider.

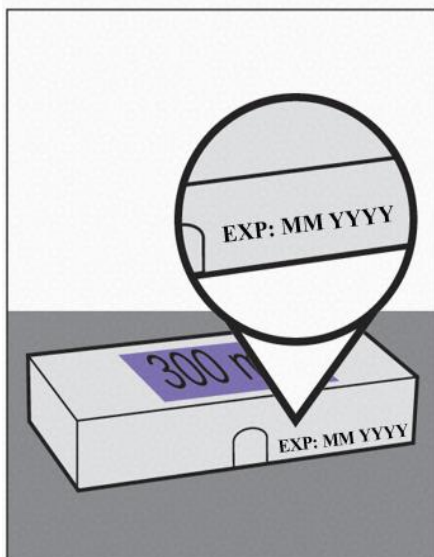


Figure F

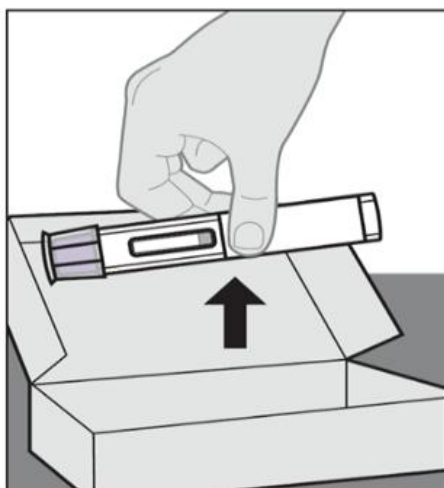


Figure G

4. Open the carton.

- 4.a. Wash your hands with soap and water.
- 4.b. 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.

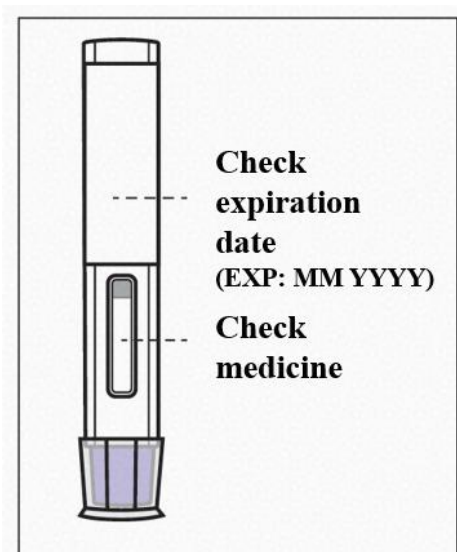


Figure H

5. Check the pre-filled pen.

- 5.a. 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.
- 5.b. Check the expiration date on the pre-filled pen.
 - **Do not** use the pre-filled pen if the expiration date has passed.
- 5.c. 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.
- 5.d. 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 16**) and contact your healthcare provider.

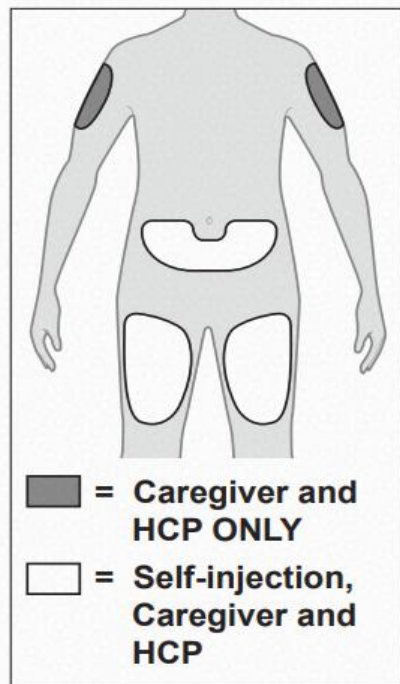


Figure I

6. Choose an injection site (see Figure I)

6.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).

6.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 the upper arm by yourself.
- **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 injection site are at least 2 cm apart from each other.

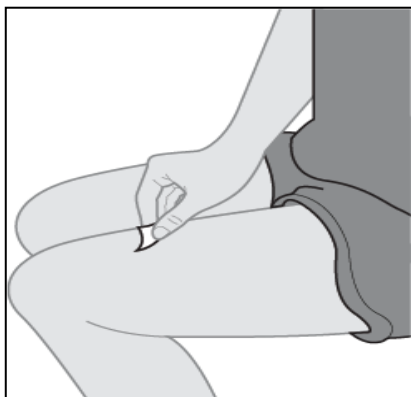


Figure J

7. Clean the injection site.

7.a. 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

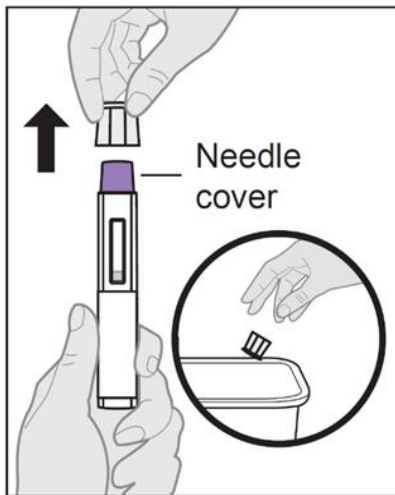


Figure K

8. Remove the Cap.

- 8.a. 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.
- 8.b. Throw away the cap in regular household trash.
- **Do not** clean or touch the needle cover at the tip of the pre-filled pen.

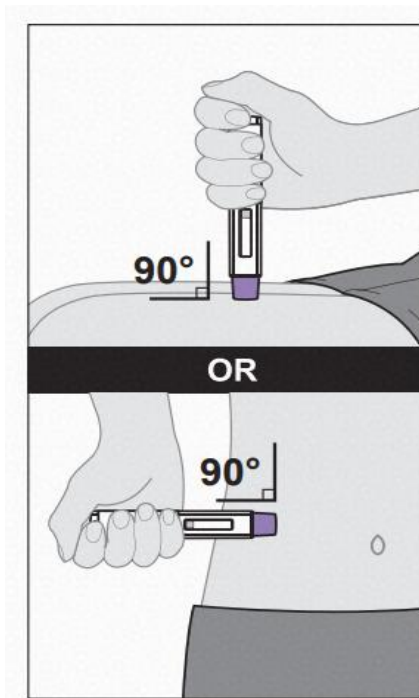


Figure L

9. Position the pre-filled pen.

- 9.a. Hold the pre-filled pen comfortably with the needle cover directly against the skin and position it so you can see the viewing window.
- 9.b. Without pinching or stretching the skin, place the pre-filled pen against the skin at a 90-degree angle (see **Figure L**).

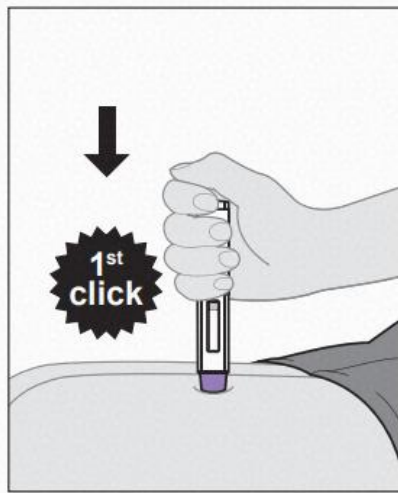


Figure M

10. Start the injection.

- 10.a. 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**)
- 10.b. 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.

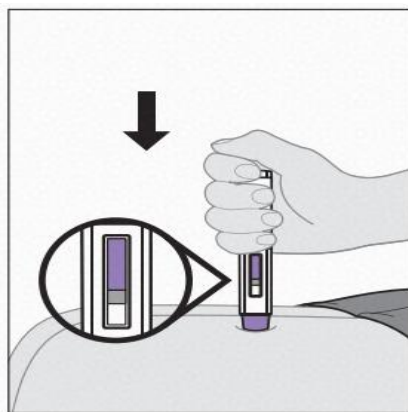


Figure N

11. Monitor the injection using the lavender indicator.

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

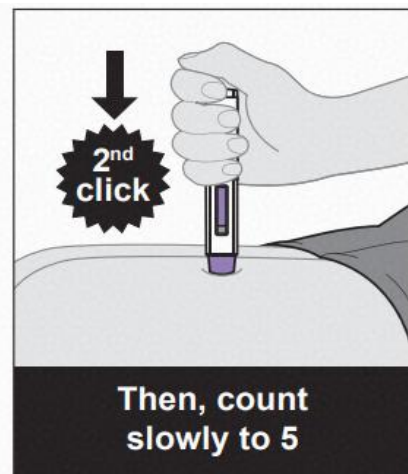


Figure O

12. Complete the injection.

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

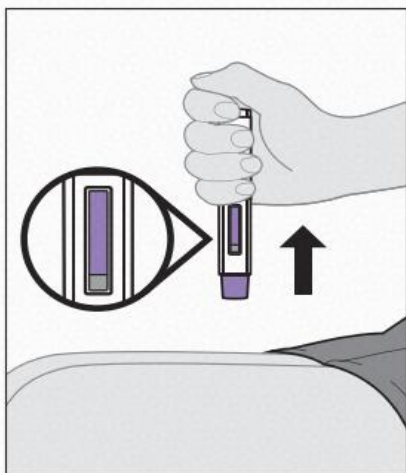


Figure P

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

13.a. 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 the needle.

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

14. Care for the injection site.

14.a. 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.

14.b. In the case of skin contact with the medicine, wash the area that touched the medicine with water.

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

15.a. Throw away the used pre-filled pen as described in **Step 16** and **Figure Q**.

15.b. Repeat **Step 2 through Step 14** for the next injection using a new pre-filled pen.

- Choose a different injection site for each new injection **at least 2 cm** from other injection sites.
- 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. Throw away (dispose of) pre-filled pen.

16.a. Put the used pre-filled pen and other supplies in a sharps disposal container right away after use (see **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 your 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.