

Package leaflet: Information for the user

Omlyclo 150 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).

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.

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 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) are not expected to self-administer Omlyclo. However, if considered appropriate by their doctor, a caregiver may give them their Omlyclo injection after proper training.

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 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, 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 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.
- The other ingredients are L-arginine hydrochloride, L-histidine hydrochloride monohydrate, L-histidine, Polysorbate 20 and water for injections.

What Omlyclo looks like and contents of the pack

Omlyclo solution for injection is supplied as a clear to 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.

Not all pack sizes may be marketed in your country.

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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.

This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Children (6 to less than 12 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.

Omlyclo Pre-filled Syringes are available in **2 dose strengths** (see *Figure A*). These instructions are to be used for the 150 mg/1 mL dose strength. The type of Pre-filled Syringe you receive depends on the dose prescribed by your healthcare provider (see *Figure C: Dosing Chart*). Check the label on the carton and the color of the Plunger rod to make sure that the dose strength is correct.

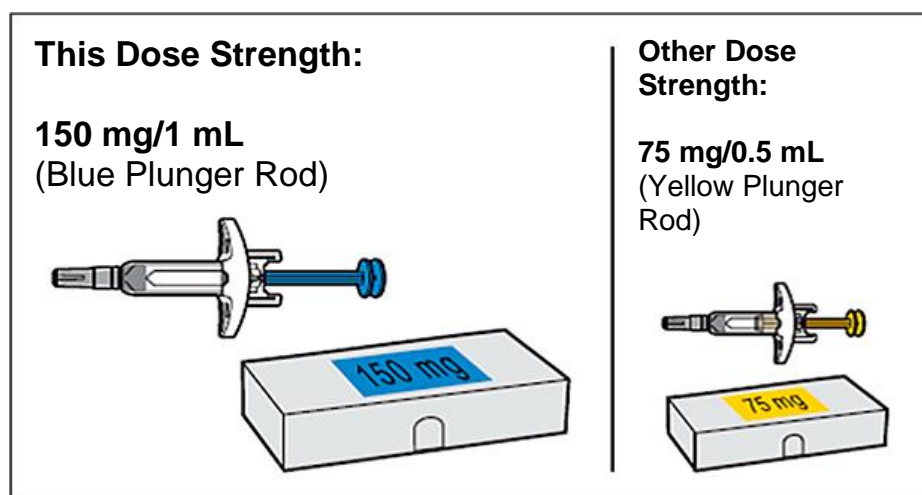


Figure A

Important safety information

- **Keep the Pre-filled Syringe out of the sight and reach of children. Pre-filled Syringe contains small parts.**
- **Do not** open the sealed carton until you are ready to use the Pre-filled Syringe.
- **Do not** use the Pre-filled Syringe if either the seal on the carton or the seal of the plastic tray is broken, as it may not be safe for you to use.
- Never leave the Pre-filled Syringe where others might tamper with it.
- **Do not** shake the Pre-filled Syringe.
- **Do not** remove the Cap until just before you give the injection.
- The Pre-filled Syringe cannot be re-used. Dispose of the used Pre-filled Syringe immediately after use in a sharps disposal container (see step **13. Dispose of the Pre-filled Syringe**).

Storing the Pre-filled Syringe

- Store the Pre-filled Syringe in a refrigerator between 2 °C and 8 °C. Store this medicine sealed inside its carton to protect it from light.
- **Do not** freeze the Pre-filled Syringe.
- Remember to take the Pre-filled Syringe out of the refrigerator and allow it to reach room temperature (25 °C), about 30 minutes, before preparing it for injection. Leave the Pre-filled Syringe in the carton to protect it from light.
- The time that the Pre-filled Syringe is kept at room temperature (25 °C) before use must not exceed 7 days.
- **Do not** use the Pre-filled Syringe after the expiration date which is stated on the carton and the Pre-filled Syringe label. If it has expired, return the entire pack to the pharmacy.
- **Do not** use the Pre-filled Syringe if it has been dropped or is visibly damaged.

Parts of the Pre-filled Syringe (see *Figure B*)

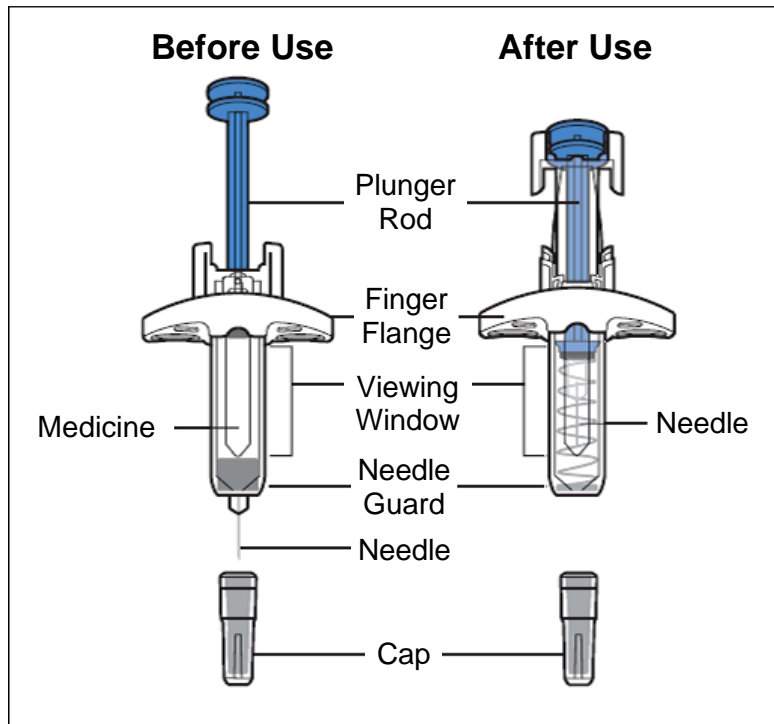


Figure B

Preparing for the Injection

Dose (mg)	Prefilled Syringes Needed	
	Yellow (75 mg/0.5 mL)	Blue (150 mg/1 mL)
75	1	0
150	0	1
225	1	1
300	0	2
375	1	1
450	0	3
525	1	2
600	0	4

Figure C

1. Gather the supplies for the injection

- 1.a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- 1.b. Take the carton(s) containing the Pre-filled Syringe(s) needed to administer your prescribed dose out of the refrigerator.

Note: Depending on the dose prescribed to you by your healthcare provider you may need to prepare one or more Pre-filled Syringes and inject the contents of them all. The following chart shows how many injections of each dose strength are needed for your prescribed dose (see *Figure C: Dosing Chart*).

1.c. Make sure you have the following supplies:

- Carton containing Pre-filled Syringe

Not included in the carton:

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

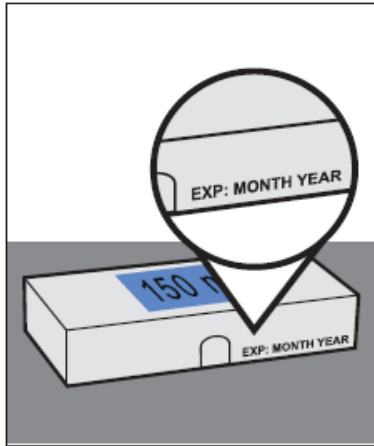


Figure A

2. Check the expiration on the carton (see *Figure D*).

- **Do not** use it if the expiration date has passed. If the expiration date has passed, return the entire pack to the pharmacy.

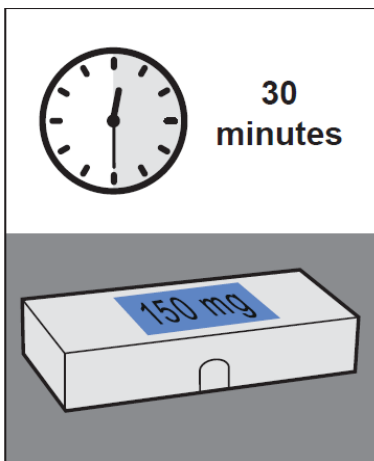


Figure B

3. Wait 30 minutes.

3.a. Leave the **unopened** carton containing the Pre-filled Syringe at room temperature (25°C) for 30 minutes to allow it to warm up (see *Figure E*).

- **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 .

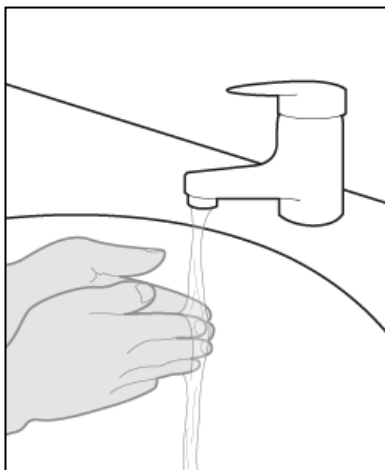


Figure C

4. Wash your hands.

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

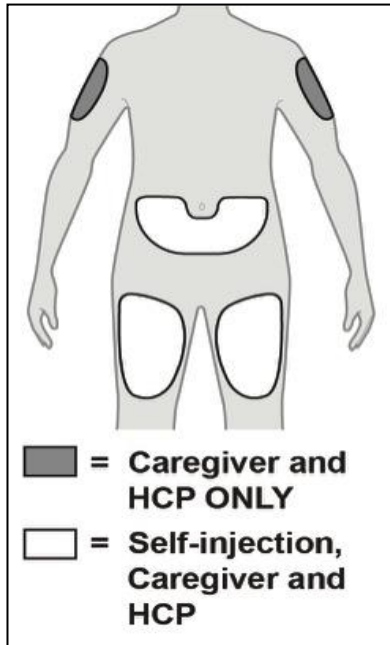


Figure D

5. Choose an injection site (see *Figure G*)

- 5.a. You may inject into:
- The front of your thighs.
 - Your lower abdomen except for the 5 cm around the belly button (navel).
 - The outer area of the upper arm if you are a caregiver or healthcare provider (HCP).
- **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 your clothes.
- 5.b. Choose a different injection site for each new injection at least 2.5 cm away from the area used for the last injection.

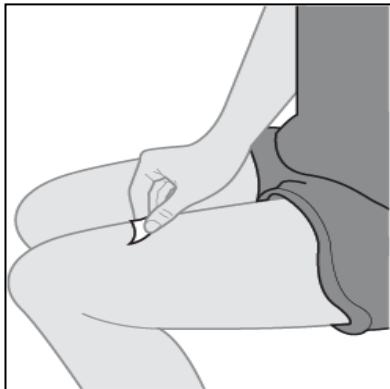


Figure E

6. Clean the injection site.

- 6.a. Clean the injection site with an alcohol swab using a circular motion (see *Figure H*).
- 6.b. Let the skin dry before injecting.
- **Do not** blow on or touch the injection site again before giving the injection.

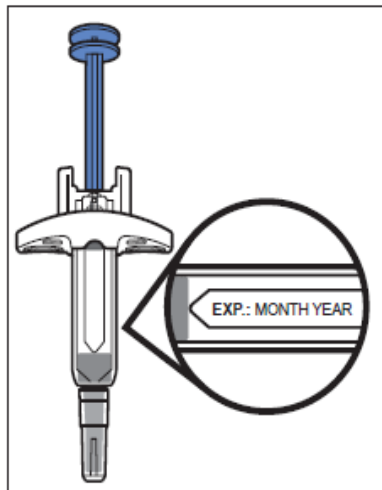


Figure F

7. Inspect the Pre-filled Syringe.

- 7.a. Open the carton.
Gripping from the syringe body lift the Pre-filled Syringe from the tray.
- 7.b. Look at the Pre-filled Syringe and make sure you have the correct Medicine (Omyclo) and dosage.
- 7.c. Look at the Pre-filled Syringe and make sure it is not cracked or damaged.
- 7.d. 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.

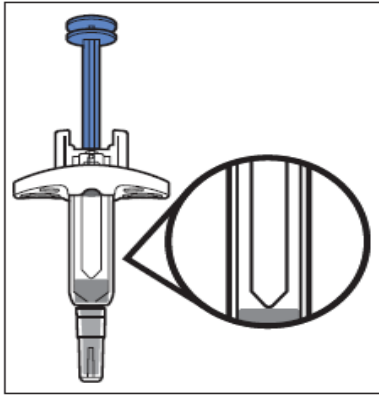


Figure G

8. Inspect the Medicine.

- 8.a. Look at the Medicine and confirm that the liquid is clear to cloudy, colourless to pale brownish-yellow, and free of particles (see *Figure J*).
- **Do not** use the Pre-filled Syringe if the liquid is discolored, distinctly cloudy, or contains particles in it.
 - You may see air bubbles in the liquid. This is normal.

Administering the Injection

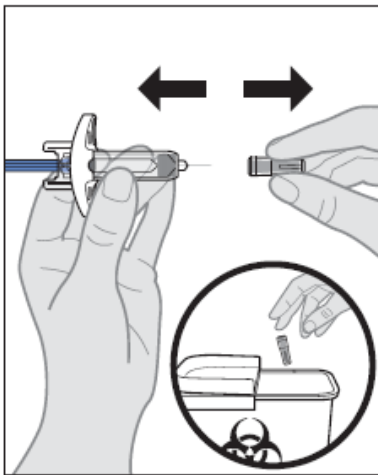


Figure H

9. Remove the Cap.

- 9.a. Hold the Pre-filled Syringe by the syringe body in one hand. Gently pull the Cap straight off with the other hand.
- **Do not** hold the Plunger rod while removing the Cap.
 - You may see a drop of liquid at the tip of the Needle. This is normal.
- 9.b. Dispose of the Cap right away in a sharps disposal container (see step 13. **Dispose of the Pre-filled Syringe** and *Figure K*).
- **Do not** re-cap the Pre-filled Syringe.
 - **Do not** remove the Cap until you are ready to inject.
 - **Do not** touch the Needle. Doing so may result in a needle stick injury.

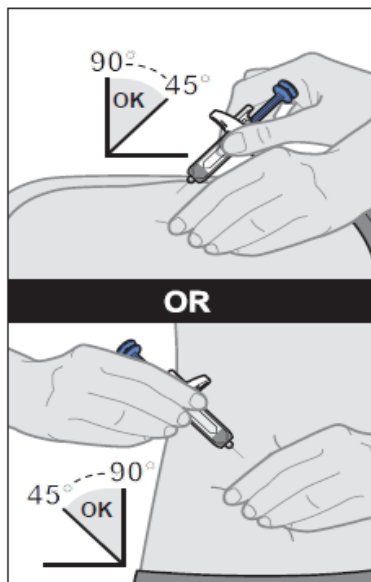


Figure I

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

- 10.a. Gently pinch a fold of skin at the injection site with one hand.
- 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).
- 10.b. With a quick and “dart-like” motion, insert the Needle completely into the fold of skin at a 45 to 90-degree angle (see *Figure L*).
- **Do not** touch the Plunger rod while inserting the needle into the skin.

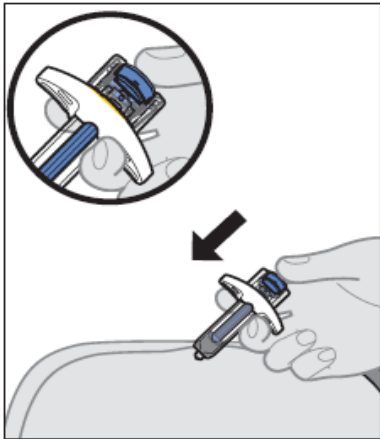


Figure J

11. Give the injection.

- 11.a. After the Needle is inserted, release the pinch.
- 11.b. Slowly push the Plunger rod **all the way down** until the full dose of medicine gets injected, and the syringe is empty (see *Figure M*).

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

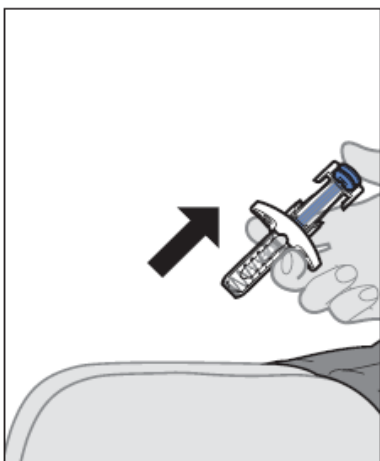


Figure K

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

- 12.a. After the Pre-filled Syringe is empty, slowly lift your thumb from the Plunger rod until the Needle is completely covered by the Needle Guard (see *Figure N*).

- If the Needle is not covered, proceed carefully to dispose of the syringe (see step **13. Dispose of the Pre-filled Syringe**).
- Some bleeding may occur (see step **14. Care for the injection site**).
- In case of skin contact with Medicine, wash the area that touched the Medicine with water.
- **Do not** reuse the Pre-filled Syringe.
- **Do not** rub the injection site.

After the injection

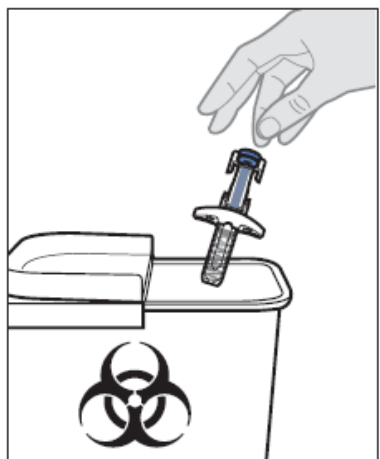


Figure L

13. Dispose of the Pre-filled Syringe.

- 13.a. Put the used Pre-filled Syringe in a sharps disposal container right away after use (see *Figure O*).

- **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. For the safety and health of you and others, needles and used syringes must never be re-used. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
- **Do not** throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

14. Care for the injection site.

14.a. If some bleeding occurs, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.