PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Omlyclo®

Solution for Injection in a Pre-filled Syringe

Active ingredient and its concentration: Omalizumab 150 mg/mL

Each pre-filled syringe of Omlyclo contains 150 mg/mL omalizumab.

Inactive and allergenic ingredients in the product: see section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

Omlyclo is a biosimilar product. For further information about biosimilar products, refer to the Ministry of Health website: https://www.gov.il/he/Departments/General/biosimilar

1. WHAT IS THE MEDICINE INTENDED FOR?

Allergic asthma:

Omlyclo is indicated for patients aged 6-12 years with persistent severe asthma and patients aged 12 years and above with moderate to severe persistent asthma, who have a positive skin test or a lab response to a perennial respiratory allergen and whose symptoms are not adequately controlled with inhaled corticosteroids. Omalizumab has shown reduced incidence of asthma flare-ups in these patients.

Limitations of use:

Omlyclo is not indicated for relief of acute bronchospasm or of status asthmaticus (asthma attack that lasts for more than 24 hours). Omlyclo is not indicated for treatment of other allergic conditions.

Chronic rhinosinusitis (inflammation of the nose and sinuses) with nasal polyps:

Omlyclo in combination with intranasal corticosteroids is indicated for the treatment of severe chronic rhinosinusitis with nasal polyps in adults (18 years of age and older) who did not achieve adequate control of the disease with intranasal corticosteroids.

Chronic spontaneous urticaria:

Omlyclo is indicated as an adjunct treatment for chronic spontaneous urticaria in adult and adolescent (12 years of age and older) patients with an inadequate response to H1 antihistamine treatment.

Therapeutic group: Medicines for obstructive airway diseases, other systemic medicines for obstructive airway diseases.

Omlyclo works by blocking a substance called immunoglobulin E (IgE) that 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 chronic spontaneous urticaria.

Nasal polyps are small lumps on the nasal mucosa. Omlyclo helps to reduce their size and improves symptoms including nasal congestion, loss of sense of smell, post-nasal drip (at the back of the throat) and runny nose.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient omalizumab or to any of the additional ingredients contained in the medicine (listed in section 6 "Further information").

If you think you may be allergic to one of the ingredients, tell your doctor since you should not be given Omlyclo.

Special warnings regarding use of the medicine:

Before treatment with Omlyclo, tell the doctor if:

- you have kidney or liver problems.
- you have a disorder where your own immune system attacks parts of your own body (autoimmune disease).
- you are traveling to a region where infections caused by parasites are common, since Omlyclo may weaken your resistance to such infections.
- you have had a previous severe allergic reaction (anaphylaxis) caused, for example, by 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 intended for the prevention or treatment of other types of allergy conditions, such as sudden allergic reactions, hyperimmunoglobulin E syndrome (Job's syndrome, an inherited immune disorder), aspergillosis (a fungus-related lung disease), food allergy, eczema or hay fever, since Omlyclo has not been studied in these conditions.

Pay attention to signs of allergic reactions and other serious side effects:

Omlyclo may cause serious side effects. You must look out for signs of these conditions while using Omlyclo. Seek medical care immediately if you notice signs indicating severe allergic reactions or other serious side effects. Such signs are listed under "Serious side effects" in section 4. The majority of the severe allergic reactions occur within the first 3 doses of Omlyclo.

Children and adolescents:

Allergic asthma

Omlyclo is not intended for children under 6 years of age. Use of the medicine in children under 6 years of age has not been studied.

Chronic rhinosinusitis with nasal polyps

Omlyclo is not intended for children and adolescents under 18 years of age. Use of the medicine in patients under 18 years of age has not been studied.

Chronic spontaneous urticaria

Omlyclo is not intended for children under 12 years of age. Use of the medicine in children under 12 years of age has not been studied.

Drug interactions:

If you are taking, or have recently taken, or if you may take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor, nurse or pharmacist. Especially 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 breastfeeding:

If you are pregnant, think you may be pregnant or are planning to become pregnant, tell your doctor before starting to use Omlyclo. Your doctor will discuss with you the benefits and potential risks of using this medicine during pregnancy.

If you become pregnant while using the medicine, tell your doctor immediately.

Omlyclo can pass into breast milk. If you are breastfeeding or plan to breastfeed, tell your doctor before using Omlyclo.

Driving and operating machinery:

It is unlikely that Omlyclo will affect your ability to drive and operate machinery.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the product according to the doctor's instructions.

Check with the doctor, nurse or pharmacist if you are uncertain about the dosage and treatment regimen of the product. Omlyclo is given in an injection under the skin (subcutaneous injection).

Instructions for injection by healthcare professionals are detailed in English at the end of the leaflet in the section **"Information for the healthcare professional"**.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

Allergic asthma and chronic rhinosinusitis with nasal polyps

Your doctor will decide on the Omlyclo dosage you need and how often the medicine will be given to you. This will depend on your body weight and the results of blood tests carried out before the start of the treatment to measure the IgE level in your blood.

You will receive between one and four injections each time, once in two weeks or once in four weeks.

Continue taking your current medicine for asthma and/or chronic rhinosinusitis with nasal polyps during the course of treatment with Omlyclo. Do not stop taking any other medicine for asthma or chronic rhinosinusitis with nasal polyps without speaking to your doctor.

You may not see an immediate improvement after starting treatment with Omlyclo. In patients with chronic rhinosinusitis with nasal polyps, the effect was seen 4 weeks after starting treatment. In patients with asthma, it usually takes between 12 and 16 weeks until the full effect is achieved.

Chronic spontaneous urticaria

You will receive two injections of 150 mg each time, every four weeks.

Continue taking your current medicine for chronic spontaneous urticaria during the course of treatment with Omlyclo. Do not stop taking any medicine without first speaking to your doctor.

Use in children and adolescents

Allergic asthma

Omlyclo can be given to 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-dosage steroid inhalers and beta-agonist inhalers. The doctor will calculate the Omlyclo dosage your child needs and how often it needs to be given. This will depend on his body weight and the results of his blood tests to measure IgE level, carried out before the start of the treatment.

Chronic rhinosinusitis with nasal polyps

Omlyclo should not be given to children and adolescents under 18 years of age.

Chronic spontaneous urticaria

Omlyclo can be given to adolescents aged 12 years and older who are already receiving antihistamines, but whose chronic spontaneous urticaria symptoms are not well controlled by these medicines. The dosage for adolescents aged 12 years and older is identical to that of adults.

Do not exceed the recommended dose.

Mode of administration

Instructions on how to use and inject Omlyclo are provided in English later in the leaflet, in the section **"Information for the healthcare professional"**. Omlyclo will be given to you as an injection under the skin (subcutaneous) by a doctor or nurse. Carefully follow all the instructions that will be given to you by your doctor or nurse.

If you forgot to take the medicine

If you missed an appointment, contact your doctor or clinic/medical center as soon as possible to re-schedule. Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

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

However, if you are being treated for chronic spontaneous urticaria, your doctor may periodically stop treatment with Omlyclo so that your symptoms can be evaluated. Follow your doctor's instructions.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Omlyclo may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. The side effects caused by Omlyclo are usually mild to moderate but may sometimes be serious.

Serious side effects:

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

Rare side effects – effects that occur in 1-10 users in 10,000:

- Severe allergic reactions (including anaphylaxis). Symptoms may include rash, itching or hives on the skin, swelling of the face, lips, tongue, larynx, windpipe or other parts of the body, rapid heartbeat, dizziness and lightheadedness, confusion, shortness of breath, wheezing or trouble breathing, bluing of the skin or lips, collapse and loss of consciousness.

  If you have a history of severe allergic reactions (anaphylaxis) that are unrelated to Omlyclo, you may be at a higher 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.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- Churg-Strauss syndrome or hypereosinophilic syndrome. The 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 cell (excess eosinophils), worsened breathing problems, 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.

Additional side effects include:

Very common side effects – effects that occur in more than one user in ten:

- Fever (in children).

Common side effects – effects that occur in 1-10 users in 100:

- Reactions at the injection site, including pain, swelling, itching and redness.
- Pain in the upper part of the stomach.
- Headache (very common in children).
- Upper respiratory tract infections, such as pharyngitis and cold.
- Pressure or pain in the cheeks and forehead (sinusitis, headaches caused by the sinuses).
- Joint pain.
- Feeling dizzy.

Uncommon side effects – effects that occur in 1-10 users in 1,000:

- Feeling sleepy or tired.
- Tingling or numbness in the hands or feet.
- Fainting, low blood pressure while sitting or standing (postural hypotension), flushing.
- Sore throat, coughing, acute breathing problems.
- Nausea, diarrhea, indigestion.
- Itching, hives, rash, increased sensitivity of the skin to sun.
- Weight gain.
- Flu-like symptoms.
- Swollen arms.

Rare side effects – effects that occur in 1-10 users in 10,000:

- Parasitic infection.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- Muscle pain and joint swelling.
- Hair loss.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report side effects of drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il.

They can also be reported to Padagis through the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:**
  Store refrigerated (2°C-8°C). Do not freeze. Store in the original package to protect from light. Can be stored at a temperature of up to 25°C for up to 7 days. Mark the date it was taken out of the refrigerator on the carton package.
- Do not use a package that is damaged or looks as if it was tampered with.
- Do not use the product if the syringe fell on a hard surface or fell after removing the needle shield.
- Do not shake the syringe.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: L-arginine hydrochloride, L-histidine hydrochloride monohydrate, L-histidine, Polysorbate 20 and water for injection.

What the medicine looks like and the contents of the package:

A pre-filled syringe containing a clear to opalescent, colorless to pale brownish-yellow solution.

Each package contains one 0.5 mL (75 mg omalizumab) pre-filled syringe or one, 6 or 10 1 mL (150 mg omalizumab) pre-filled syringes for single use.

The 0.5 mL (75 mg omalizumab) pre-filled syringe has a yellow plunger rod, while the 1 mL (150 mg omalizumab) pre-filled syringe has a blue plunger rod.

Not all package sizes may be marketed.

Manufacturer and address: Celltrion Ltd., Incheon, South Korea.

Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

Revised in August 2025.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 17984.38402

מידע לצוות הרפואי
معلومات للطاقم الطبي
INFORMATION FOR THE HEALTHCARE PROFESSIONAL

המידע הבא מיועד לאנשי הצוות הרפואי בלבד:
المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط:

The following information is intended for healthcare professionals only:

INSTRUCTIONS FOR USE OF OMLYCLO®

Read ALL the way through these instructions before injecting. The box contains Omlyclo pre-filled syringe(s).

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. See *Figure C: Dosing Chart*.

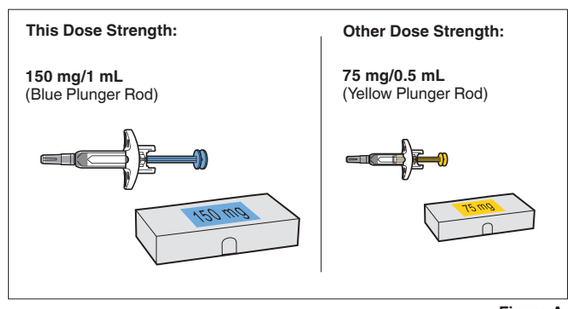

Figure A

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 it looks damaged or used.
- **Do not** use the pre-filled syringe if the carton is damaged or seal is broken.
- 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.
- 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** 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*)

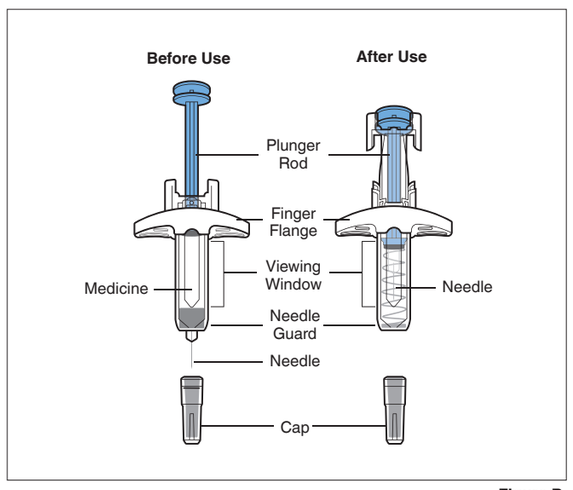

Figure B

Preparing for the Injection

Dose (mg)	Pre-filled Syringes Needed	
	Yellow (75 mg/0.5 mL)	Blue (150 mg/1 mL)
75	1	
150		1
225	1 +	1
300		2
375	1 +	2
450		3
525	1 +	3
600		4

Figure C: Dosing Chart

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 the prescribed dose out of the refrigerator.
Note: Depending on the dose 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 the 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

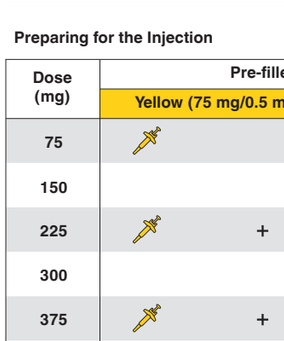

Figure D

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.

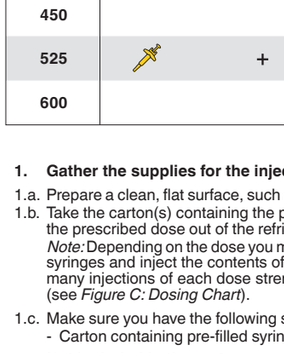

Figure E

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.

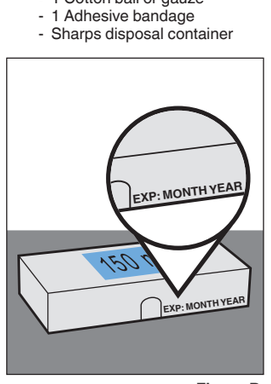

Figure F

4. Wash your hands.

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

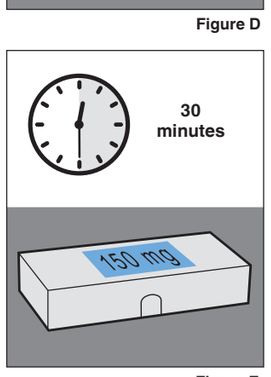

Figure G

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

5.a. You may inject into:
- The front of the thighs.
- The lower abdomen except for the 5 cm around the belly button (navel).
- The outer area of the upper arm.

- **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 the clothes.

5.b. Choose a different injection site for each new injection at least 2 cm apart from the area used for the last injection.

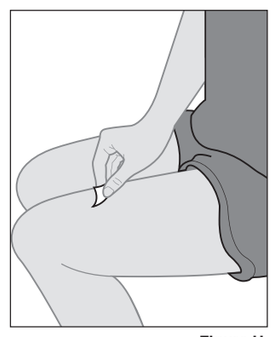

Figure H

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.

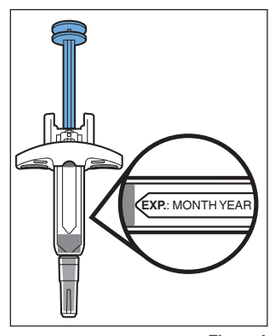

Figure I

7. Inspect the pre-filled syringe.

7.a. Open the carton.
Gripping from the syringe body lift the pre-filled syringe from the carton.

7.b. Look at the pre-filled syringe and make sure you have the correct medicine (Omlyclo) 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.

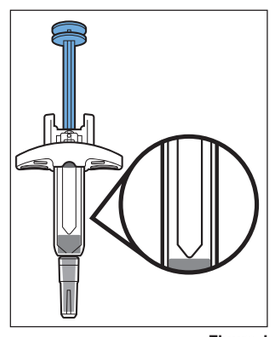

Figure J

Administering the Injection

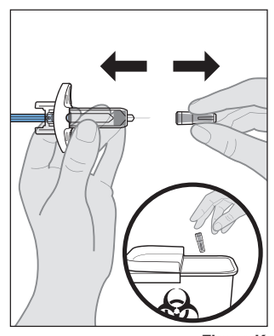

Figure K

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 few drops 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.

8. Inspect the medicine.

8.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.

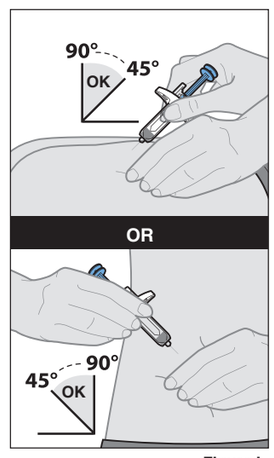

Figure L

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.

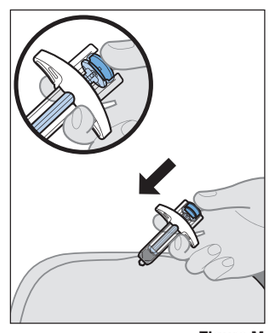

Figure M

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.

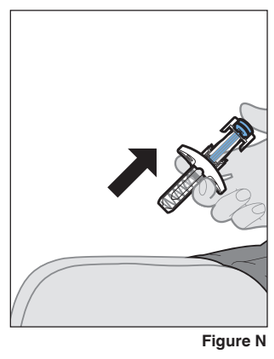

Figure N

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 O

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*).
- 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.

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.