

Omyclo[®]

Omalizumab (75mg/0.5ml and 150mg/1.0ml) solution for injection in pre-filled syringe

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What Omyclo is used for

Allergic Asthma (adults and adolescents – 12 years of age and above)

Omyclo (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS).

Allergic Asthma (children – 6 to < 12 years of age)

Omyclo is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Omyclo has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Omyclo is used to treat CRSwNP in adults (18 years of age and older) whose disease is not well controlled with their current CRSwNP medicines. Omyclo helps reduce the size of the polyps and

improves symptoms caused by CRSwNP including nasal congestion, loss of sense of smell, post-nasal drip and runny nose.

Chronic Spontaneous Urticaria (CSU)

Omyclo is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

How it works

Allergic Asthma and CRSwNP

Omyclo works by blocking a substance called immunoglobulin E (also known simply as IgE) which is produced by your body. IgE contributes to a type of inflammation that plays a key role in causing allergic asthma and CRSwNP. Your doctor will measure the amount of IgE in your blood before starting the treatment with Omyclo.

Chronic Spontaneous Urticaria (CSU)

Omyclo works by blocking a substance called immunoglobulin E (also known simply as IgE) which is produced by your body. As a consequence the activity of specific receptors and/or cells in your body which play a key role in causing chronic spontaneous urticaria are reduced. This leads to a reduction of your symptoms, like itching and hives.

Before you use Omyclo

– When you must not use it

- If you are allergic to omalizumab or any of the ingredients of Omyclo listed at the end of this leaflet.
- If you think you may be allergic, ask your doctor for advice.

– Before you start to use it

Warnings and precautions

Tell your doctor before you use Omyclo:

- 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 live in a region where parasite infections are frequent or traveling to such a region, Omyclo may weaken your resistance to such infections.
- If you have had a previous severe allergic reaction (anaphylaxis) resulting, for example, from a medicine, an insect bite or food.

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

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

It is important that you receive training from your doctor or healthcare professional in how to recognize early signs of severe allergic reactions, and how to manage these reactions if they occur. The majority of severe allergic reactions occur within the first 3 doses of Omyclo.

Children and adolescents

Allergic Asthma

Do not give Omyclo to children under 6. Its use in children below 6 years of age has not been studied sufficiently.

CRSwNP

Do not give Omyclo to children and adolescents under 18. Its use in children and adolescents below 18 years of age has not been studied.

Chronic Spontaneous Urticaria

Do not give Omyclo to children under 12. Its use in children below 12 years of age has not been studied sufficiently.

Older people (65 years or above)

Omyclo may be given to people aged 65 years and over. There is no evidence to

suggest that any special precautions are needed when older people are treated, although experience is still limited.

Pregnancy

If you are pregnant or plan to become pregnant, tell your doctor before starting treatment with Omlyclo. 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 straight away.

Breast-feeding

If you are breast-feeding or intend to breast-feed, get advice from your doctor before using Omlyclo. Omlyclo may be passed in your breast milk to your baby.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Omlyclo can be used together with inhaled and/or intranasal corticosteroids and other medicines for allergic asthma, and/or CRSwNP as well as with H1 or H2 antihistamines and LTRAs for chronic spontaneous urticaria, but it is still important to tell your doctor that you are taking them before you are given Omlyclo.

How to use Omlyclo

Omlyclo is administered by injection under the skin (by subcutaneous injection).

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). 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.

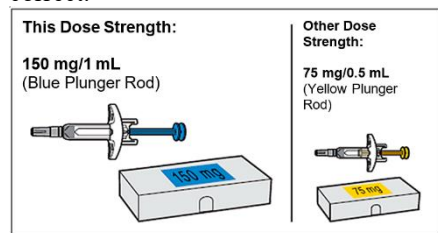


Figure A

Parts of the Pre-filled Syringe

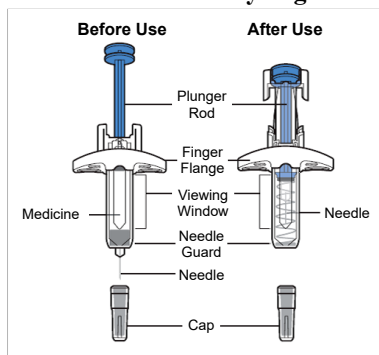


Figure B

Preparing for the injection:

1. Gather the supplies for the injection

- a) Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- 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.

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

- c) Make sure you have the following supplies:
 - Carton containing pre-filled syringe

Not included in the carton:

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

2. Check the expiration on the carton

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

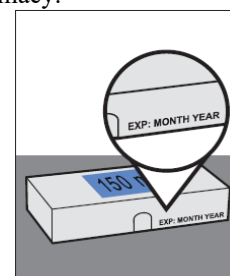


Figure D

3. Wait 30 minutes

- a) Leave the unopened carton containing the pre-filled syringe at room temperature (25°C) for 30 minutes to allow it to warm up.
 - **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.

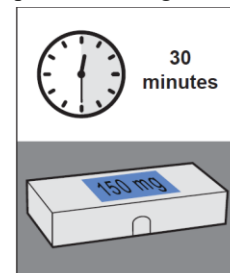


Figure E

4. Wash your hands

- a) Wash your hands with soap and water and dry them thoroughly.

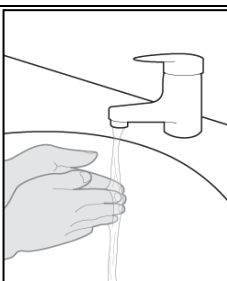


Figure F

5. Choose an injection site

- 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.
- b) Choose a different injection site for each new injection at least 2.5 cm away from the area used for the last injection.

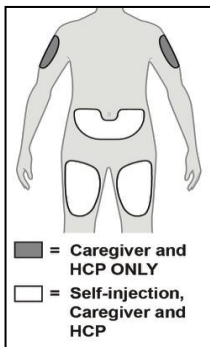


Figure G

6. Clean the injection site

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



Figure H

7. Inspect the pre-filled syringe

- a) Open the carton.
 - Gripping from the syringe body lift the pre-filled syringe from the tray.
- b) Look at the pre-filled syringe and make sure you have the correct medicine (Omlyclo) and dosage.
- c) Look at the pre-filled syringe and make sure it is not cracked or damaged.
- d) Check the expiration date on the label of the pre-filled syringe.

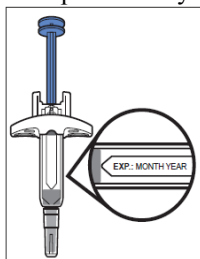


Figure I

- **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.

8. Inspect the Medicine

- a) Look at the medicine and confirm that the liquid is clear to cloudy, colourless to pale brownish-yellow, and free of particles.

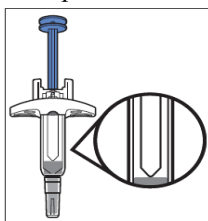


Figure J

- **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:

9. Remove the Cap

- 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.
- b) Dispose of the Cap right away in a sharps disposal container.
 - **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.

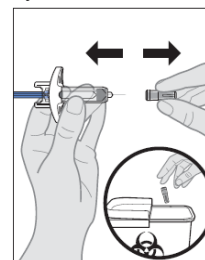


Figure K

10. Insert the pre-filled syringe into the injection site

- 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).
- 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.

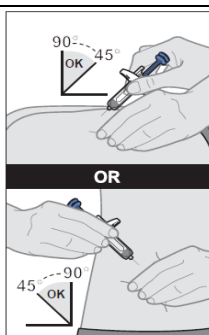


Figure L

11. Give the injection

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

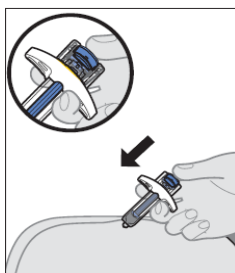


Figure M

12. 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 Needle Guard (see Figure N).
- If the Needle is not covered, proceed carefully to dispose of the 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.

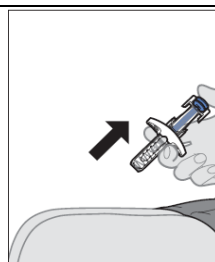


Figure N

After the injection:

13. Dispose of the pre-filled syringe

- a) Put the used pre-filled syringe in a sharps disposal container right away after use (see Figure O).
- Note:* For further details on “Disposal”, see section ‘Storage and Disposal of Omlyclo’ at the end of this leaflet.



Figure O

14. Care for the injection site

- 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.

– *How much to use*

Allergic Asthma and CRSwNP

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 as prescribed by your doctor.

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

Chronic Spontaneous Urticaria

You will need 1 or 2 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.

– *When to use it*

Use as directed by your doctor or pharmacist.

– *How long to use it*

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

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

Allergic Asthma and CRSwNP

You may not see an immediate improvement in your asthma after beginning Omlyclo therapy. It usually takes several weeks to have the full effect.

– *If you forget to use it*

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

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

– *If you use too much (overdose)*

If you accidentally use more Omlyclo than prescribed, please contact your doctor for further advice.

While you are using it

– *Things you must do*

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 should be given by or under the supervision of a healthcare professional (see Section ‘Before you use Omlyclo’).

- 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.

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

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

– *Things you must not do*

You should not use Omlyclo to prevent or treat other allergy-type conditions:

- sudden allergic reactions
- *hyperimmunoglobulin E syndrome* (an inherited immunodeficient disorder)
- *aspergillosis* (a fungus-related lung disease)
- food allergy, allergic skin rash or hay fever.

You should not use Omlyclo to treat acute asthma symptoms, like a sudden asthma attack. You will have been given a separate medicine for this.

– *Things to be careful of*

If you stop using Omlyclo

Interrupting or ending the treatment with Omlyclo may lead to recurrence of your asthma or CSU symptoms.

If you have any further questions on the use of Omlyclo, ask your doctor, pharmacist or healthcare provider.

Side effects

As with all medicines, patients treated with Omlyclo can experience side effects, although not everybody gets them.

Some side effects can be serious.

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

Rare: *may affect up to 1 in every 1,000 people*

Omlyclo contains a protein, and as with any protein, local or systemic allergic reactions may potentially occur. Sudden severe allergic reactions have been rarely reported. If you notice sudden signs of allergy such as 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, shortness of breath, wheezing or trouble breathing, tell your doctor immediately.

Not known: *frequency cannot be estimated from the available data*

- Low blood platelet count with symptoms such as bleeding or bruising more easily than normal (signs of so-called "thrombocytopenia").
- Joint appearance of some of the following symptoms: Pain, numbness or tingling in the arms and legs, lumps or raised patches in the skin, weakness and fatigue, loss of appetite and weight loss (signs of so-called "Churg-Strauss syndrome").
- Joint appearance of some of the following symptoms: Joint pain, stiffness, rash, fever, swollen/enlarged lymph nodes (signs of so-called serum-sickness). When it occurs this is usually between one to five days after injection.

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common: *may affect more than 1 in 10 people*

- fever (in children)

Common: *may affect up to 1 in every 10 people*

- reactions at the injection site including pain, swelling, itching and redness

- pain in the upper part of the abdomen (in children)
- headache (very common in children)
- feeling dizzy
- sore throat and blocked nose (nasopharyngitis)
- feeling of pressure or pain in the cheeks and forehead (sinusitis and sinus headache)
- upper respiratory tract infection, such as inflammation of the pharynx and common cold
- burning sensation or pain when passing urine and having to urinate frequently (possible symptom of an urinary tract infection)
- pain in upper or lower limbs (arms and/or legs)
- pain in muscles and/or bones and/or joints (musculoskeletal pain, myalgia, arthralgia)

Uncommon: *may affect up to 1 in every 100 people*

- feeling sleepy or tired
- tingling or numbness of the hands or feet
- fainting, postural hypotension (low blood pressure while sitting or standing), flushing
- sore throat, coughing, acute breathing problems
- nausea, diarrhea, 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 every 1000 people*

- parasite infections

Not known: *frequency cannot be estimated from the available data*

- joint swelling
- hair loss

If you notice any other side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare provider.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

– *MAL number*
MALXXXXXXXXX

Storage and Disposal of Omlyclo

– *Storage*

- Store in a refrigerator (2°C – 8°C). Do not freeze.
- Store in the original package in order to protect from light.
- Omlyclo must be kept out of the reach and sight of children.

Disposal

- **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.

Manufacturer

CELLTRION Pharm, Inc.
82, 2 Sandan-ro, Ochang-eup,
Cheongwon-gu, Cheongju-si,
Chungcheongbuk-do, 28117, Republic
of Korea

Batch Releaser

CELLTRION, Inc., Plant 2
20, Academy-ro, Yeonsu-gu, Incheon,
22014, Republic of Korea

Product Registration Holder

Celltrion Healthcare Malaysia Sdn. Bhd.
Unit 32-01, Level 32 Tower B,
The Vertical Corporate Tower,
Avenue 10, Bangsar South,
No. 8, Jalan Kerinchi,
59200 Kuala Lumpur
Malaysia

Date of revision

08/08/2025

Serial Number

NPRA (R3)25/96

Product Description

– *What it looks like*

Omlyclo is a clear to cloudy, colourless to pale brownish-yellow solution, which is supplied as a single use pre-filled syringe.

Omlyclo 75mg/0.5ml solution for injection in pre-filled syringe

Packs of:

- 1 pre-filled syringe

Omlyclo 150mg/1.0ml solution for injection in pre-filled syringe

Packs of:

- 1 pre-filled syringe

– *Ingredients*

The active substance is omalizumab.

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