

Confidence is the **ONLY** way



Get to know OMLYCLO, the first and only FDA-approved biosimilar interchangeable with Xolair[®] (omalizumab)

OMLYCLO is an injectable prescription medicine used to treat:

- **Moderate to severe persistent asthma** in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens. It is not known if OMLYCLO is safe and effective in people with asthma under 6 years of age.
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)** in people 18 years of age and older when medicines to treat CRSwNP called nasal corticosteroids have not worked well enough. It is not known if OMLYCLO is safe and effective in people with CRSwNP under 18 years of age.
- **Food allergy** in people 1 year of age and older to reduce allergic reactions that may occur after accidentally eating one or more foods to which you are allergic. While taking OMLYCLO you should continue to avoid all foods to which you are allergic. It is not known if OMLYCLO is safe and effective in people with food allergy under 1 year of age.
- **Chronic spontaneous urticaria (CSU, previously referred to as chronic idiopathic urticaria (CIU), chronic hives without a known cause)** in people 12 years of age and older who continue to have hives that are not controlled with H1 antihistamine treatment. It is not known if OMLYCLO is safe and effective in people with CSU under 12 years of age.

OMLYCLO should not be used for the emergency treatment of any allergic reactions, including anaphylaxis, to treat other forms of hives, or sudden breathing problems.

OMLYCLO: What you need to know

Why did my doctor prescribe OMLYCLO?

Your doctor prescribed OMLYCLO to treat your inflammatory condition. OMLYCLO has been shown to help:



Moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids.



Chronic rhinosinusitis with nasal polyps (CRSwNP) in people 18 years of age and older when medicines to treat CRSwNP called nasal corticosteroids have not worked well enough.



Food allergy in people 1 year of age and older to reduce allergic reactions that may occur after accidentally eating one or more foods to which you are allergic.



Chronic spontaneous urticaria (CSU) in people 12 years of age and older who continue to have hives that are not controlled with H1 antihistamine treatment.

OMLYCLO, like Xolair®, works by blocking an antibody called immunoglobulin E (IgE)

OMLYCLO works by attaching to IgE to calm an allergic response. When your body has an allergic reaction, your immune system overreacts and produces IgE. In simple terms, OMLYCLO helps interrupt part of the allergic process that may be contributing to symptoms.

IMPORTANT SAFETY INFORMATION continued

OMLYCLO may cause serious side effects, including:

Severe allergic reactions (anaphylaxis) can happen when you receive OMLYCLO. The reaction can occur after the first dose, or after many doses. It may also occur right after an OMLYCLO injection or days later. Anaphylaxis is a life-threatening condition and can lead to death.

OMLYCLO: What you need to know

OMLYCLO is a prescription biosimilar

OMLYCLO is the first and only biosimilar interchangeable with Xolair®. A biosimilar means that:

- OMLYCLO has been shown to be highly similar to Xolair, an FDA-approved biologic medication
- There are no clinically meaningful differences in how it works or how safe it is compared with Xolair

Some biosimilars, including OMLYCLO, are considered “interchangeable.” An interchangeable biosimilar has gone through added FDA review to demonstrate it is highly similar to the original biologic and meets FDA standards for switching. This means you can switch between the interchangeable biosimilar and the original biologic and expect it to work just as well and be just as safe. An interchangeable biosimilar may be substituted by your pharmacist without changing your prescription.*



A biosimilar is typically more affordable than the reference product.

*Subject to state law.

IMPORTANT SAFETY INFORMATION continued

Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

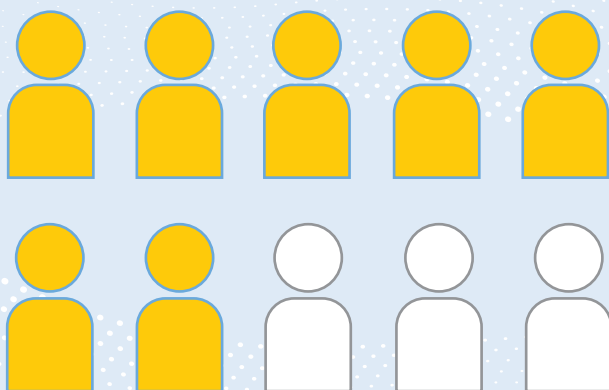
How OMLYCLO can help you

OMLYCLO was shown to be as effective and safe as Xolair®

In a clinical study of 619 people with chronic spontaneous urticaria (CSU), OMLYCLO was shown to be as effective as Xolair in reducing itch.

People receiving both OMLYCLO and Xolair had meaningful improvement in itch severity at 12 weeks.

By week 12, about 7 out of 10 people
had meaningful itch relief



- More than 1 out of 3 people reported well-controlled symptoms; and about 1 in 4 people had no recorded hives or itch during the weekly scoring period

IMPORTANT SAFETY INFORMATION continued

Your healthcare provider will monitor you closely for symptoms of an allergic reaction while you are receiving OMLYCLO and for a period of time after treatment is initiated. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction.

What is OMLYCLO?

OMLYCLO is approved to treat other diseases it has not been directly tested on in studies. The FDA looks at a wide variety of tests and data to determine that a drug is biosimilar to a reference product, including clinical trials, blood and immune-system evaluations, and chemical analyses. **OMLYCLO has been approved by the FDA as the first and only biosimilar for Xolair®.**

As the first and only biosimilar for Xolair, OMLYCLO offers:



Similar results: OMLYCLO works in the same way as Xolair, and is as safe and as effective



No interruption of care: OMLYCLO and Xolair have the same active ingredient (omalizumab) and are given the same way



Interchangeability: OMLYCLO has been approved to be interchangeable with Xolair by the FDA, which means OMLYCLO can be used in its place, without any disruption



Support services that can help with coverage, prior authorization, injection support, and co-pay assistance

In the same clinical study for chronic spontaneous urticaria (CSU), OMLYCLO was found to be as safe and well tolerated as Xolair.

IMPORTANT SAFETY INFORMATION continued

Cancer. Cases of cancer were observed in some people who received OMLYCLO.

Inflammation of your blood vessels. Rarely, this can happen in people with asthma who receive OMLYCLO. Tell your healthcare provider right away if you have: rash, chest pain, shortness of breath, a feeling of pins and needles or numbness of your arms or legs.

Side effects for OMLYCLO

OMLYCLO may cause the same serious side effects as Xolair, including a severe allergic reaction called anaphylaxis. Like Xolair, it can happen after your first dose or after many doses, and right after an injection or even days later. Get emergency help right away if you have trouble breathing, chest tightness, dizziness, fainting, hives, swelling of the throat or tongue, or trouble swallowing. Because of this risk, treatment is started in a healthcare setting and patients are monitored after treatment begins.

Other serious side effects of both OMLYCLO and Xolair may include

- cancer
- inflammation of the blood vessels
- fever, muscle aches, and rash
- parasitic infection
- heart and circulation problems

Common side effects of both OMLYCLO and Xolair can vary depending on what indication they are being used to treat. These may include

- joint pain
- dizziness
- feeling tired
- itching or skin rash
- headache
- injection-site reactions
- cough or cold-like symptoms
- nausea
- fever, infections, swelling, and bone fractures

These are not all the possible side effects of treatment with either OMLYCLO or Xolair.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Celltrion USA at 1-800-560-9414.

IMPORTANT SAFETY INFORMATION continued

Fever, muscle aches, and rash. Some people get these symptoms 1 to 5 days after receiving an OMLYCLO injection. If you have any of these symptoms, tell your healthcare provider.

Parasitic infection. Some people who are at a high risk for parasite (worm) infections get a parasite infection after receiving OMLYCLO. Your healthcare provider can test your stool to check if you have a parasite infection.

IMPORTANT SAFETY INFORMATION

OMLYCLO may cause serious side effects, including:

Severe allergic reactions (anaphylaxis) can happen when you receive OMLYCLO. The reaction can occur after the first dose, or after many doses. It may also occur right after an OMLYCLO injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

Your healthcare provider will monitor you closely for symptoms of an allergic reaction while you are receiving OMLYCLO and for a period of time after treatment is initiated. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction.

Cancer. Cases of cancer were observed in some people who received OMLYCLO.

Inflammation of your blood vessels. Rarely, this can happen in people with asthma who receive OMLYCLO. Tell your healthcare provider right away if you have: rash, chest pain, shortness of breath, a feeling of pins and needles or numbness of your arms or legs.

Fever, muscle aches, and rash. Some people get these symptoms 1 to 5 days after receiving an OMLYCLO injection. If you have any of these symptoms, tell your healthcare provider.

Parasitic infection. Some people who are at a high risk for parasite (worm) infections get a parasite infection after receiving OMLYCLO. Your healthcare provider can test your stool to check if you have a parasite infection.

Heart and circulation problems. Some people who receive OMLYCLO have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving OMLYCLO, tell your healthcare provider about all of your medical conditions, including if you:

- have sudden breathing problems (bronchospasm).
- have ever had a severe allergic reaction called anaphylaxis.
- have or have had a parasitic infection.
- have or have had cancer.
- are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed. It is not known if OMLYCLO may harm your unborn baby or if it passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby while you receive and use OMLYCLO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Do not receive and use OMLYCLO if you are allergic to omalizumab products or any of the ingredients in OMLYCLO.

The most common side effects of OMLYCLO:

In adults and children 12 years of age and older with asthma: joint pain especially in your arms and legs, dizziness, feeling tired, itching, skin rash, bone fractures, and pain or discomfort of your ears.

In children 6 to less than 12 years of age with asthma: swelling of the inside of your nose, throat, or sinuses, headache, fever, throat infection, ear infection, abdominal pain, stomach infection, and nose bleeds.

In adults with chronic rhinosinusitis with nasal polyps: headache, injection site reactions, joint pain, upper abdominal pain, and dizziness.

In people with chronic spontaneous urticaria: nausea, headaches, swelling of the inside of your nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.

In people with food allergy: injection site reactions and fever.

These are not all the possible side effects of OMLYCLO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What to expect during treatment with OMLYCLO

OMLYCLO can be given at home



OMLYCLO is available in single-dose*, prefilled syringe injections that offer you the flexibility and control of self-administration.



You'll be shown how to use the prefilled syringe by your doctor or a specialized nurse so you can give yourself the injection at home.



Most people inject OMLYCLO every 2 or 4 weeks.

OMLYCLO prefilled syringes are available in 3 dose strengths

75 mg/0.5 mL



150 mg/1 mL



300 mg/2 mL



*Some dosage strengths require multiple injections.

IMPORTANT SAFETY INFORMATION continued

Heart and circulation problems. Some people who receive OMLYCLO have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision.

What to expect during treatment with OMLYCLO

OMLYCLO can also be given by a healthcare professional

OMLYCLO may be given as an injection under the skin by a healthcare provider in a healthcare setting. Your doctor will monitor you after treatment begins.

The starting dose and frequency for OMLYCLO depend on what you are being treated for.

Dosing		
Indication	OMLYCLO Dosing Range	Dosing Frequency
Asthma (Adults and pediatric patients 6 years of age and older)	75 to 375 mg	Every 2 or 4 weeks
Chronic rhinosinusitis with nasal polyps (Adults 18 years of age and older)	75 to 600 mg	Every 2 or 4 weeks
Food allergy (Adults and pediatric patients 1 year of age and older)	75 to 600 mg	Every 2 or 4 weeks
Chronic spontaneous urticaria (Adults and adolescents 12 years of age and older)	150 or 300 mg	Every 4 weeks

Your doctor will determine the dose appropriate for you.

IMPORTANT SAFETY INFORMATION continued

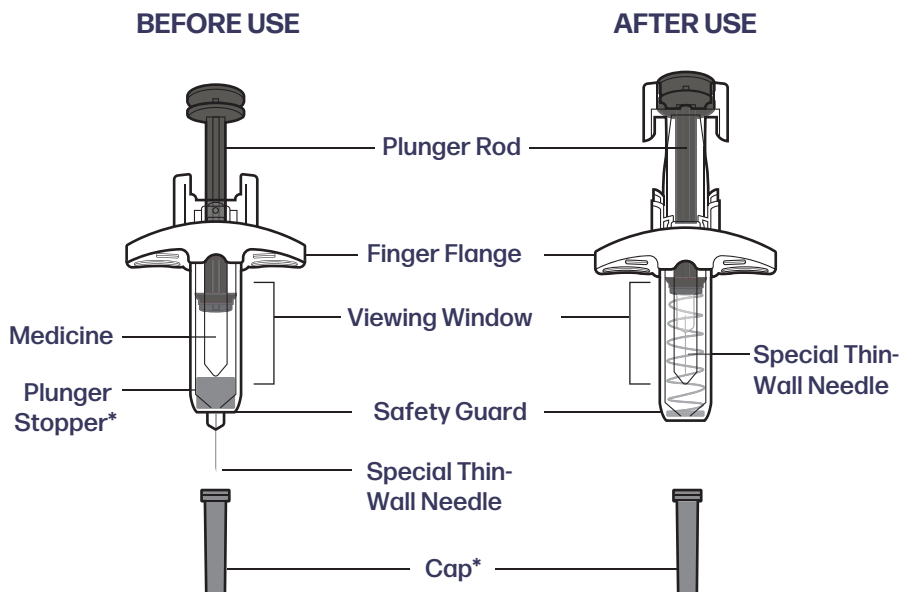
Before receiving OMLYCLO, tell your healthcare provider about all of your medical conditions, including if you:

- have sudden breathing problems (bronchospasm).
- have ever had a severe allergic reaction called anaphylaxis.

How to administer OMLYCLO

Designed for safe and efficient administration

For added safety, the OMLYCLO safety guard helps protect against accidental needle sticks. Its easy-to-hold design also makes injections simpler and more comfortable, even with one hand.



*The syringe plunger stopper and needle cap are not made with natural rubber latex.

IMPORTANT SAFETY INFORMATION continued

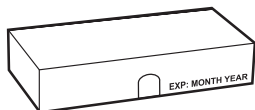
- have or have had a parasitic infection.
- have or have had cancer.
- are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed. It is not known if OMLYCLO may harm your unborn baby or if it passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby while you receive and use OMLYCLO.

How to administer OMLYCLO

How to self-inject OMLYCLO

1. Prepare for the injection

- 1a. Remove carton from refrigerator**



- Take the carton containing the prefilled syringe out of the refrigerator

- 1b. Gather your supplies**



Cotton ball/gauze and alcohol swab



Adhesive bandage



FDA-cleared sharps disposal container

- 1c. Let syringe reach room temperature**



30-45 minutes

- Allow the prefilled syringe to come to room temperature for 30-45 minutes

- 1d. Wash and dry your hands**



- Wash and dry your hands
- Check your syringe carefully:
 - Do not use if it is damaged or expired
 - Do not use if the medication looks cloudy, discolored, or contains particles

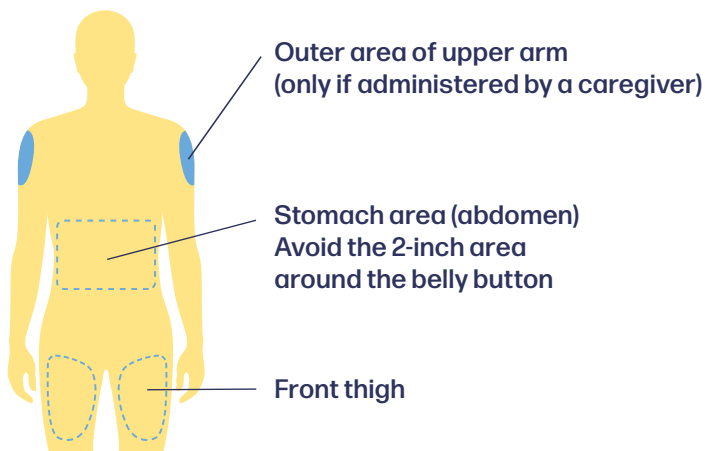
IMPORTANT SAFETY INFORMATION continued

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Do not receive and use OMLYCLO if you are allergic to omalizumab products or any of the ingredients in OMLYCLO.

How to administer OMLYCLO

1e. Choose and clean the injection site



DO NOT inject through:



clothing



moles



scars



bruises



tender skin

If your dose requires more than 1 injection, choose a different injection site for each injection.

IMPORTANT SAFETY INFORMATION continued

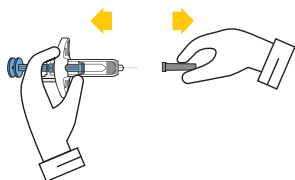
The most common side effects of OMLYCLO:

In adults and children 12 years of age and older with asthma: joint pain especially in your arms and legs, dizziness, feeling tired, itching, skin rash, bone fractures, and pain or discomfort of your ears.

How to administer OMLYCLO

2. Give the injection

2a. Remove the syringe cap



- Hold the body of the prefilled syringe and gently remove the cap with your other hand

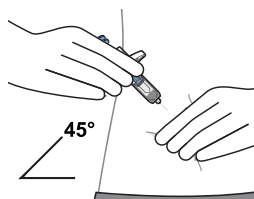
2b. Dispose of syringe cap



- Dispose of the cap in your sharps container*
- *Do not recap or touch the needle.

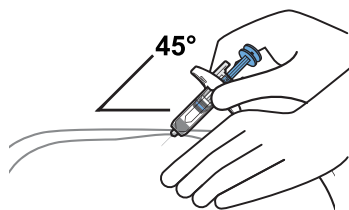
3. How to inject

3a. Insert the needle



- Pinch a fold of skin at the injection site and insert the needle into the fold at a 45° angle

3b. Use the correct needle angle for injection

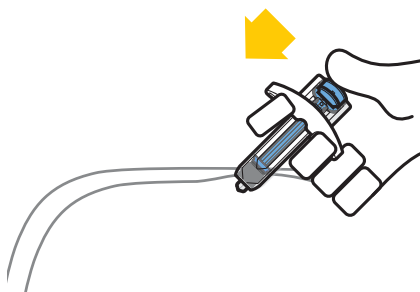


IMPORTANT SAFETY INFORMATION continued

In children 6 to less than 12 years of age with asthma: swelling of the inside of your nose, throat, or sinuses, headache, fever, throat infection, ear infection, abdominal pain, stomach infection, and nose bleeds.

How to administer OMLYCLO

4a. Inject the medicine



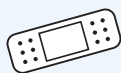
- Inject the medication. Keep the skin pinched until you complete the injection

4b. Dispose of the syringe



- Remove the prefilled syringe from the injection site and dispose in your FDA-cleared sharps disposal container

Care for the injection site



- If bleeding occurs, gently press the area with the cotton ball or gauze. Do not rub. Apply the adhesive bandage if needed

IMPORTANT SAFETY INFORMATION continued

In adults with chronic rhinosinusitis with nasal polyps: headache, injection site reactions, joint pain, upper abdominal pain, and dizziness.

In people with chronic spontaneous urticaria: nausea, headaches, swelling of the inside of your nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.

In people with food allergy: injection site reactions and fever.

Celltrion Support Programs

These programs help you get better access to OMLYCLO



Help verify your insurance coverage for OMLYCLO, determine your plan-specific requirements, and understand your available benefits.



Got a prescription? Check your eligibility for the Celltrion CARES Co-pay Program.

If eligible, you may pay as little as \$0* out of pocket for each dose.



*Only for commercially insured patients. Eligibility criteria and program maximums apply. Please see full [Terms and Conditions](#).

IMPORTANT SAFETY INFORMATION

OMLYCLO may cause serious side effects, including:

Severe allergic reactions (anaphylaxis) can happen when you receive OMLYCLO. The reaction can occur after the first dose, or after many doses. It may also occur right after an OMLYCLO injection or days later. Anaphylaxis is a life-threatening condition and can lead to death.

Celltrion Support Programs (continued)

These programs help you get better access to OMLYCLO



A Nurse Connector is a registered healthcare professional who can help you along your OMLYCLO treatment journey.*

Support you can expect from a Nurse Connector includes

- Injection training to help you get started and become comfortable taking OMLYCLO
- Education about OMLYCLO storage and handling, dosing schedule, and injection site rotation
- Ongoing support for as long as you need to be confident in your use of OMLYCLO

[Click here to learn more about Celltrion support programs](#)

Enroll in [Celltrion CONNECT](#) or call 1-877-812-6662, Monday – Friday between 8 AM – 8 PM ET.

*While Nurse Connectors are registered healthcare professionals, they cannot offer medical advice. If you have an urgent or specific question related to your healthcare, please contact your HCP.

IMPORTANT SAFETY INFORMATION continued

Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

Confidence
is the **ONLY** way

IMPORTANT SAFETY INFORMATION continued

Your healthcare provider will monitor you closely for symptoms of an allergic reaction while you are receiving OMLYCLO and for a period of time after treatment is initiated. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction.

Please see Important Safety Information throughout and on pages 7-8.
Please read the Medication Guide for key information on serious side effects.

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