

MEDICATION GUIDE

OMLYCLO® (OM-ly-clo)

(omalizumab-igec)

injection, for subcutaneous use

What is the most important information I should know about OMLYCLO?

OMLYCLO may cause serious side effects, including:

Severe allergic reaction. A severe allergic reaction called 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 a 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.

What is OMLYCLO?

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.

OMLYCLO should also not be used to treat other forms of hives, or sudden breathing problems.

Who should not receive and use OMLYCLO?

Do not receive and use OMLYCLO if you:

- are allergic to omalizumab products or any of the ingredients in OMLYCLO. See the end of this Medication Guide for a complete list of ingredients in OMLYCLO.

What should I tell my healthcare provider before receiving OMLYCLO?

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. It is not known if OMLYCLO may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OMLYCLO 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.

How should I receive and use OMLYCLO?

- When starting treatment OMLYCLO should be given by your healthcare provider in a healthcare setting.
- If your healthcare provider decides that you or a caregiver may be able to give your own OMLYCLO prefilled syringe injections, you should receive training on the right way to prepare and inject OMLYCLO.
- Do not try to inject OMLYCLO until you have been shown the right way to give OMLYCLO prefilled syringe injections by a healthcare provider. Use OMLYCLO exactly as prescribed by your healthcare provider. For children 12 years of age and older, OMLYCLO prefilled syringe may be self-injected under adult supervision. For children 1 to 11 years of age, OMLYCLO prefilled syringe should be injected by a caregiver.
- See the detailed Instructions for Use that comes with OMLYCLO for information on the right way to prepare and inject OMLYCLO.
- OMLYCLO is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks.

- In people with asthma, CRSwNP and food allergy, a blood test for a substance called IgE must be performed before starting OMLYCLO to determine the appropriate dose and dosing frequency.
- In people with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
- Do not decrease or stop taking any of your other asthma, CRSwNP, hive medicine, food allergy medicine or allergen immunotherapy unless your healthcare providers tell you to.
- You may not see improvement in your symptoms right away after OMLYCLO treatment. If your symptoms do not improve or get worse, call your healthcare provider.
- If you inject more OMLYCLO than prescribed, call your healthcare provider right away.

What are the possible side effects of OMLYCLO?

OMLYCLO may cause serious side effects, including:

- See **"What is the most important information I should know about OMLYCLO?"**
- **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. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by OMLYCLO. Tell your healthcare provider right away if you have:
 - o rash
 - o chest pain
 - o shortness of breath
 - o 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 a 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. It is not known whether these are caused by 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.

How should I store OMLYCLO?

- Store OMLYCLO in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep your unused OMLYCLO prefilled syringes in the original carton until use to protect them from light.
- OMLYCLO prefilled syringe can be removed from and placed back in the refrigerator if needed. The total combined time out of refrigerator may not be more than 7 days. Do not use if OMLYCLO prefilled syringe is left at temperatures above 77°F (25°C) and discard in a FDA-cleared sharps disposal container.
- Do not freeze. Do not use if OMLYCLO prefilled syringes have been frozen.
- Do not shake.
- Keep OMLYCLO out of direct sunlight.
- Do not use OMLYCLO past the expiration date.

Keep the OMLYCLO prefilled syringe, FDA-cleared sharps disposal container and all medicines out of the reach of children.

General information about the safe and effective use of OMLYCLO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use OMLYCLO for a condition for which it was not prescribed. Do not give OMLYCLO to other people, even if they have the same symptoms

that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about OMLYCLO that is written for health professionals.

For more information, call 800-560-9414

What are the ingredients in OMLYCLO?

Active ingredient: omalizumab-igec

Inactive ingredients:

Prefilled syringe: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, and polysorbate 20

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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