

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Omlyclo?

Omlyclo contains the active ingredient omalizumab, a monoclonal antibody produced by recombinant DNA technology. Omlyclo is used to Allergic Asthma, Chronic rhinosinusitis with Nasal Polyps (Nasal Polyps) and Chronic Spontaneous Urticaria (CSU).

For more information, see Section [1. Why am I using Omlyclo?](#) in the full CMI.

2. What should I know before I use Omlyclo?

Do not use if you have ever had an allergic reaction to omalizumab (the active ingredient in Omlyclo) or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

For more information, see Section [2. What should I know before I use Omlyclo?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Omlyclo and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Omlyclo?

- Your doctor will decide how much Omlyclo you need and how often you will need it. This depends on your body weight and the amount of IgE measured in your blood before the start of treatment.
- The recommended dose of Omlyclo to treat Allergic Asthma and CRSwNP ranges from 75 mg to 750 mg of Omlyclo either every two weeks or every four weeks. Do not stop taking any asthma and/or nasal polyps medication without talking to your doctor.
- The recommended dose of Omlyclo to treat Chronic Spontaneous Urticaria (CSU) ranges from 150 mg to 300 mg of Omlyclo every four weeks. Keep taking your current medicine for CSU during Omlyclo treatment.
- Do not stop taking any medicine without talking to your doctor. If you are being treated for CSU, your doctor may stop Omlyclo treatment from time to time so that your symptoms can be assessed.

More instructions can be found in Section [4. How do I use Omlyclo?](#) in the full CMI.

5. What should I know while using Omlyclo?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Omlyclo.Tell your doctor if you become pregnant while having treatment with Omlyclo.Keep all your doctors appointments so that you don't miss any injections and your progress can be checked.
Things you should not do	<ul style="list-style-type: none">Do not stop using any medicine without talking to your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Omlyclo affects you.
Looking after your medicine	<ul style="list-style-type: none">Store at 2°C to 8°C. Refrigerate. Do not freeze.Protect from light by storing in original carton until time of use.The product may be kept for a total of 7 days at 25°C.

For more information, see Section [5. What should I know while using Omlyclo?](#) in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: Signs of an allergic reaction, such as wheezing, chest tightness and cough, a raised itchy red rash (hives), swollen lips, tongue, eyes or face, stomach pain, feeling sick, vomiting or diarrhoea; Signs of severe allergic reaction, swelling of the throat and mouth, difficulty breathing, lightheadedness, confusion, blue skin or lips and collapsing and losing consciousness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Omyclo*

Active ingredient: Omalizumab (rch)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Omyclo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Omyclo.**

Where to find information in this leaflet:

- [1. Why am I using Omyclo?](#)
- [2. What should I know before I use Omyclo?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Omyclo?](#)
- [5. What should I know while using Omyclo?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Omyclo?

Omyclo contains the active ingredient omalizumab.

Omyclo is a monoclonal antibody which works by blocking a substance produced by the body called immunoglobulin E (or IgE). IgE contributes to a type of inflammation that is involved in causing symptoms of asthma and nasal polyps. Your doctor will measure the amount of IgE in your blood before starting your treatment with Omyclo.

Omyclo is used to:

- Prevent or relieve the symptoms of allergic asthma in adults and paediatric patients (children and adolescents) 6 years and over who are already using preventer puffers containing steroids.
- Treat nasal polyps in adults (18 years of age and older) whose severe disease is not well controlled with their current nasal polyp medicines.
- Treat Chronic Spontaneous Urticaria in adults and adolescents (12 years of age and older) whose CSU symptoms are not well controlled by antihistamines.

2. What should I know before I use Omyclo?

Warnings

Do not use Omyclo if:

- You are allergic to omalizumab, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- Wheezing or shortness of breath
- Severe rash, itching or hives on the skin
- Swelling of the face, lips, tongue, larynx (voice box), windpipe which may cause difficulty in swallowing or

- breathing, or other parts of the body
- fast heartbeat, dizziness and light headedness

- Always check the ingredients to make sure you can use this medicine.

Tell your doctor if you get severe allergic reactions (called anaphylaxis) to any medicines, foods, dyes, preservatives, bee stings, insect bites etc.

Check with your doctor if you:

Have any other medical conditions such as:

- Kidney or liver problems
- Autoimmune disease
- If you live in a region where parasite infections are frequent, Omyclo may weaken your resistance to such infections.
- If you have had a previous severe allergic reaction (anaphylaxis) resulting, for example, from medicine, an insect bite or food.
- A low platelet count (thrombocytopenia)

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them.

Look out for signs of allergic reactions and other serious side effects. This medicine can cause such reactions.

It is important that you receive training from your doctor or healthcare professional on how to recognise early signs of severe allergic reactions, and how to manage these reactions if they occur – see "Side effects". The majority of severe allergic reactions occur within the first 3 doses, and within the first hour of taking Omyclo.

See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

There is not much information on the use of Omlyclo during pregnancy or breast-feeding. If it is necessary for you to have this medicine, your doctor will discuss with you the benefits and risks involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Omalizumab has been used together with inhaled and/or intranasal corticosteroids other common medicines for asthma/or nasal polyps, as well as H1 or H2 antihistamines and LTRAs for chronic spontaneous urticaria.

Some medicines may interfere with Omlyclo and affect how it works.

It is possible that some medicines and Omlyclo could interfere with each other. Your doctor or pharmacist can advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Omlyclo.

4. How do I use Omlyclo?

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 amount of IgE measured in your blood before the start of treatment.

- You will need 1 to 4 injections at a time.
- The recommended dose ranges from 75 mg to 750 mg of Omlyclo either every two weeks or every four weeks as prescribed by your doctor.

Keep taking your current asthma and/or nasal polyps medicine during Omlyclo treatment.

Do not stop taking any asthma and/or nasal polyps medication without talking to your doctor.

After 16 weeks, if your symptoms are well controlled, your doctor may be able to reduce or stop other asthma and/or nasal polyps medicines that you are taking. Your doctor will discuss this with you.

Chronic spontaneous urticaria

- You will need 1 to 2 injections of 150 mg 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.

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 the instructions provided and use Omlyclo until your doctor tells you to stop.

When to use Omlyclo

- Omlyclo should be used as advised by your doctor.
- Omlyclo is given as a subcutaneous injection. This means that it is injected into the fatty tissue just under the skin.
- Omlyclo pre-filled syringe is designed to be administered by patients or carers or healthcare professional.
- The injections are usually given in the upper arm or thigh.

Injecting Omlyclo

You and your doctor will decide if you should inject Omlyclo yourself.

The first 3 doses is recommended to be given by or under the supervision of a healthcare professional.

How to inject Omlyclo from a pre-filled syringe (75 mg or 150 mg)

Read all the way through these instructions before injecting.

Children (6 to less than 12 years of age) are not expected to inject Omlyclo themselves, however, if deemed appropriate by their healthcare provider, a caregiver may give them their injections after proper training.

Omlyclo is 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 colour of the Plunger rod to make sure that the dose strength is correct.

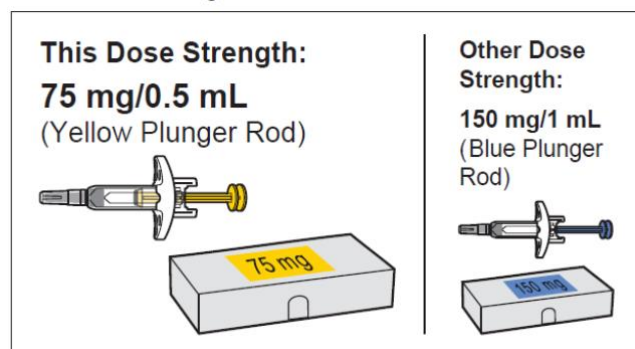


Figure A

Parts of the Pre-filled syringe (see Figure B)

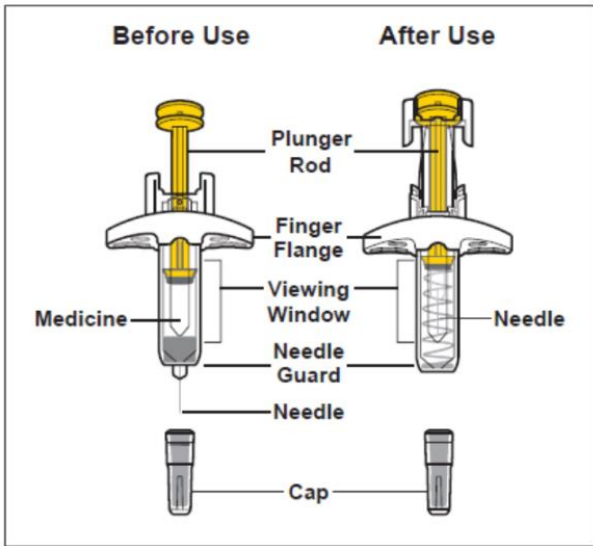


Figure B

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 Prefilled Syringe(s) needed to administer your prescribed dose out of the refrigerator and leave it unopened (leave the pre-filled syringe in the carton to protect from light).

Note: Depending on the dose prescribed to you by your healthcare provider you may need to prepare one or more Prefilled 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*). Please discuss with your doctor how frequent (4 weekly or 2 weekly) you need to administer each dose.

- 1.c. Make sure you have the following supplies:
 - Carton containing Prefilled Syringe

Not included in the carton:

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

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	2
450	0	3
525	1	3
600	0	4

Figure C

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.

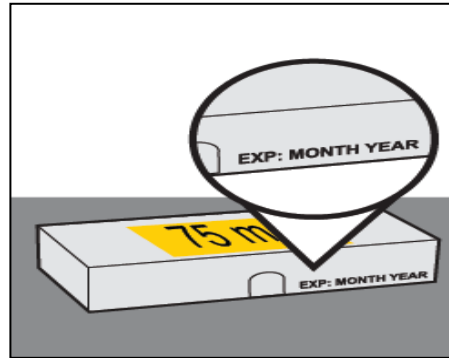


Figure A

3. Wait 20 minutes.

- 3.a. Leave the **unopened** carton containing the Prefilled Syringe at room temperature (25°C) for 20 minutes to allow it to warm up (see *Figure E*).

- **Do not** warm the Prefilled Syringe using heat sources such as hot water or a microwave.

If the Prefilled Syringe does not reach room temperature, this could cause the injection to feel uncomfortable and make it hard to push the Plunger rod.

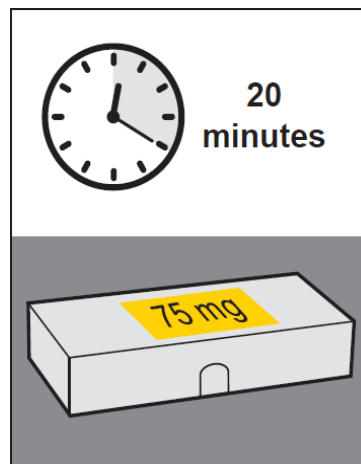


Figure B

4. Wash your hands.

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



Figure C

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 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.

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

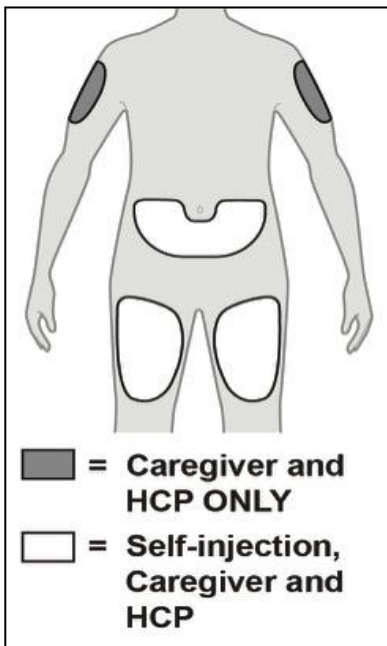


Figure D

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.

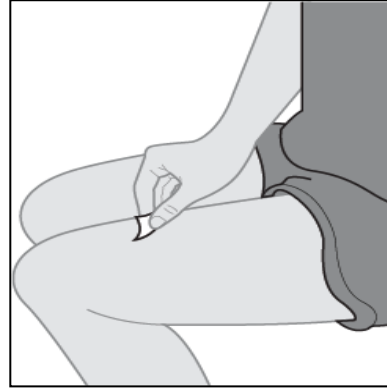


Figure E

7. Inspect the Prefilled Syringe.

- 7.a. Open the carton.
- Gripping from the syringe body lift the Prefilled Syringe from the tray.
- 7.b. Look at the Prefilled Syringe and make sure you have the correct Medicine (Omlyclo) and dosage.
- 7.c. Look at the Prefilled Syringe and make sure it is not cracked or damaged.
- 7.d. Check the expiration date on the label of the Prefilled 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 Prefilled Syringe until the expiration date becomes visible.

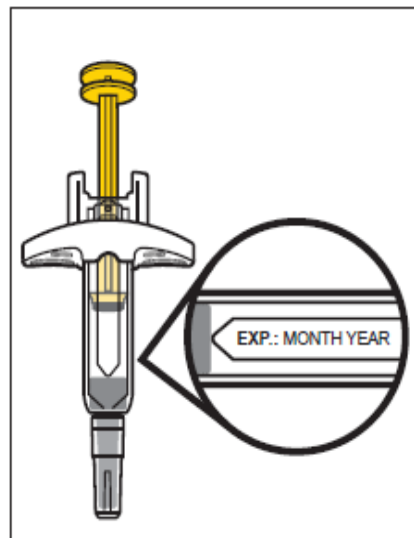


Figure F

8. Inspect the Medicine.

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

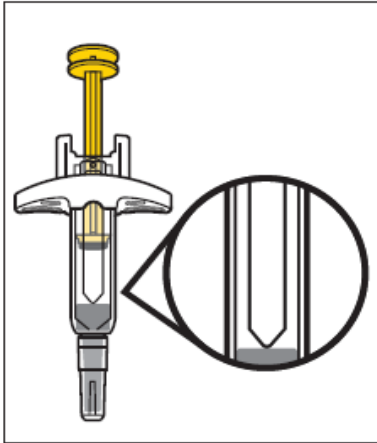


Figure G

Administering the Injection

9. Remove the Cap.

- 9.a. Hold the Prefilled 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 Prefilled Syringe** and *Figure K*).
- **Do not** re-cap the Prefilled 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.

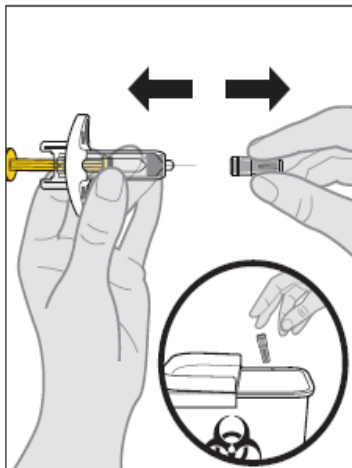


Figure H

10. Insert the needle 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 needle into the skin.
 - Push the needle all the way in to ensure that the medicine can be fully administered.

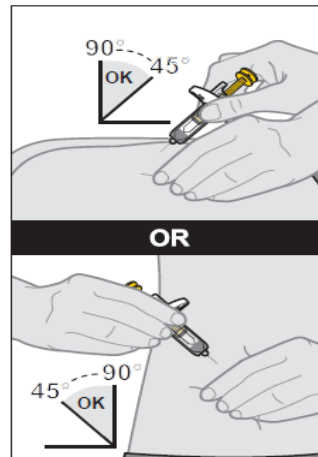


Figure I

11. Give the injection.

- 11.a. After the Needle is inserted, release the pinch. Hold the syringe as shown.
- 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 Prefilled 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.

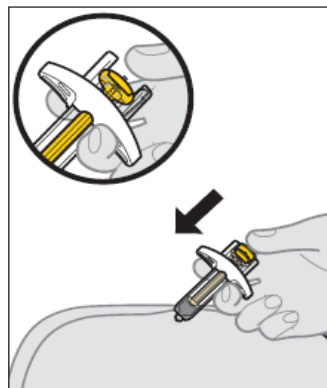


Figure J

12. Remove the Prefilled Syringe from the injection site.

- 12.a. After the Prefilled 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 Prefilled 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 Prefilled Syringe.
 - **Do not** rub the injection site.

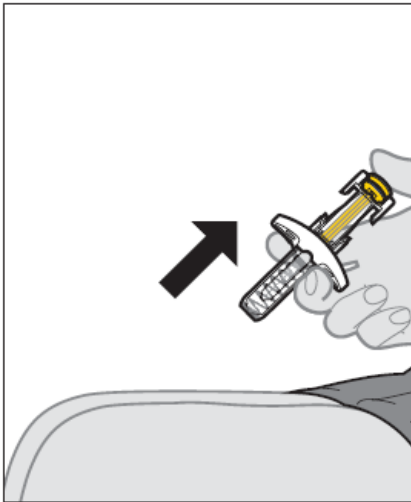


Figure K

After the injection

13. Dispose of the Prefilled Syringe.

- 13.a. Put the used Prefilled Syringe in a sharps disposal container right away after use (see *Figure O*).
- **Do not** throw away (dispose of) the Prefilled 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.



Figure L

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.

If you forget to use Omlyclo

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 Omlyclo

If you think that you have used too much Omlyclo, immediately tell your doctor for further advice.

No cases of overdose with this medicine have been reported.

For more information on the management of overdose you should contact:

- Phone the Poisons Information Centre (by calling 13 11 26), or
- Contact your doctor

5. What should I know while using Omlyclo?

Things you should do

If you become pregnant while having treatment with Omlyclo, tell your doctor.

Keep all of your doctor's appointments so that you don't miss any injections and your progress can be checked.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Omlyclo.

Remind any doctor, dentist or pharmacist you visit that you are using Omlyclo.

Things you should not do

- **Do not** stop using any medicine without talking to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Omlyclo affects you.

Looking after your medicine

- Store this medicine sealed in its outer box to protect it from light. Store in the refrigerator between 2°C and 8°C. **Do not** FREEZE.
- Prior to use, allow the syringe to reach room temperature (25°C) before preparing it for injection (it will take about 30 minutes). If necessary, the product may be returned to the refrigerator for later use. The total time that the syringe is kept at room temperature must not exceed 7 days.
- **Do not** try to warm the syringe using an external heat source.
- **Do not** use the syringe after the expiry date which is stated on the outer box and syringe label. If it has expired, return the entire pack to the pharmacy.
- **Do not** use Omlyclo if the pack is damaged or shows signs of tampering.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Keep it where young children cannot reach it.

Heat and dampness can destroy some medicines.

When to discard your medicine

- After injection, used syringes should be placed in a puncture-resistant container, like a sharps container.
- Antiseptic wipes, and other supplies can be placed in regular rubbish.
- Dispose of your sharps container according to your state or local regulations.

Getting rid of any unwanted medicine

If your doctor stops your treatment with Omlyclo or you find that it has passed the expiry date, ask your pharmacist how to dispose of medicines you no longer use.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Tell your doctor if you notice any of the following side effects and they worry you:</p> <ul style="list-style-type: none"> • bruising, redness or pain at the injection site • mild skin rash • headache • tiredness • hair loss • joint swelling • fever (very common in children) • 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 a urinary tract infection) • pain in upper or lower limbs (arms and/or legs) • pain in the upper part of the abdomen • pain in muscles and/or bones and/ or joints (musculoskeletal pain, myalgia, arthralgia) <p>Tell your doctor immediately if you notice any of the following signs:</p> <ul style="list-style-type: none"> • abnormal bleeding or bruising • 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> • wheezing, chest tightness and cough • a raised, itchy, red rash (hives) • swollen lips, tongue, eyes or face • stomach pain, feeling sick, vomiting or diarrhoea 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any signs</p>

<p>Severe allergic reactions (including anaphylaxis):</p> <p>In addition to any of the symptoms above:</p> <ul style="list-style-type: none"> • swelling of the throat and mouth • difficulty breathing • lightheadedness • confusion • blue skin or lips • collapsing and losing consciousness <p>Other types of allergic reactions:</p> <ul style="list-style-type: none"> • Serum sickness <p>Signs include joint pain, stiffness, rash, fever, swollen/enlarged lymph nodes with symptoms typically occurring within one to five days after the injection.</p> <p>Churg-Strauss syndrome has been observed in patients treated with omalizumab.</p> <p>The symptoms may include one or more of the following:</p> <ul style="list-style-type: none"> • Pain, • Numbness or tingling in the arms and the legs, • Lumps or raised patches in the skin, • Weakness and fatigue, • Loss of appetite and weight loss. 	<p>of an allergic reaction.</p> <p>Telephone 000 immediately if severe symptoms of allergic reaction (anaphylaxis) occur.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Omlyclo contains

<p>Active ingredient (main ingredient)</p>	<p>75 mg or 150 mg pre-filled syringe</p> <p>75 mg omalizumab</p> <p>150 mg omalizumab</p>
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<p>Other ingredients (inactive ingredients)</p>	<p>Histidine</p> <p>Histidine hydrochloride monohydrate,</p> <p>Polysorbate 20,</p> <p>Arginine hydrochloride,</p> <p>Water for injections</p>
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Do not take this medicine if you are allergic to any of these ingredients.

What Omlyclo looks like

Omlyclo injection for subcutaneous use is clear to slightly opalescent, colourless to pale brownish-yellow solution.

Omlyclo is available in the following strengths:

75 mg omalizumab in 0.5 mL solution in a pre-filled syringe with needle guard (AUST R 427223).

150 mg omalizumab in 1 mL solution in a pre-filled syringe with needle guard (AUST R 427224).

Not all pack sizes may be marketed.

Who distributes Omlyclo

Celltrion Healthcare Australia Pty Ltd
 Suite 13-03 31 Market Street,
 Sydney NSW 2000, Australia

Phone: 1800 325 228

This leaflet was prepared in November 2024.