

## PART III: CONSUMER INFORMATION

PrXOLAIR®  
(omalizumab)

This leaflet is part III of a three-part "Product Monograph" published when XOLAIR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XOLAIR. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.

#### What the medication is used for:

##### Asthma

##### Adults and adolescents 12 years of age and older:

XOLAIR (omalizumab) is a prescription medicine that has been shown to significantly decrease the incidence of asthma exacerbations and improve control of asthma symptoms in people who:

- Are 12 years of age and above
- Have moderate to severe persistent asthma. This means they have 1 or more of the following:
  - Asthma symptoms every day
  - Daily need for a rescue inhaler
  - 2 or more asthma attacks a week
  - 1 or more nights a week waking up with asthma symptoms
  - below-normal reading (less than 80%) from a tool called a peak flow meter, which measures how well the lungs work
- Have asthma that is triggered by year-round allergens in the air, which is confirmed by a doctor using a simple skin or blood test. This is known as allergic asthma
- Continue to have asthma symptoms even though they are taking inhaled steroids

##### Children 6 to less than 12 years of age:

XOLAIR, used as add-on therapy, has been shown to significantly decrease the rate of asthma exacerbations for children who are 6 to less than 12 years of age with moderate to severe persistent allergic asthma who continue to have asthma symptoms even though they are taking inhaled steroids and have a documented history of asthma exacerbation.

##### Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

XOLAIR is used to treat adults (18 years of age and older) with chronic rhinosinusitis with nasal polyps (CRSwNP) whose disease is not well controlled with their current CRSwNP medicines. XOLAIR 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 Idiopathic Urticaria (CIU)

XOLAIR (omalizumab) is a prescription medicine to treat Chronic Idiopathic Urticaria (CIU) in adults and adolescents (12 years of age and older) whose symptoms are not well controlled with antihistamines. XOLAIR provides relief of CIU symptoms such as skin itch and hives.

##### What it does:

##### What is allergic asthma?

Allergic asthma is how doctors describe a particular type of asthma. In people with this common condition, certain types of allergens can trigger asthma attacks and symptoms, such as coughing, wheezing, and shortness of breath.

You probably know about many of the things that can trigger your asthma. Cat or dog dander, dust mites, and cockroaches are common examples of year-round allergens. What you may not know is how something as simple as visiting a friend who has a pet can lead to an asthma attack. The reason allergens can trigger asthma attacks is due, in part, to a body chemical called IgE.

##### What is Chronic Idiopathic Urticaria (CIU)

Chronic Idiopathic Urticaria (CIU) is a skin disease whose symptoms include itching and hives for at least 6 weeks. Persistent symptoms may be daily or episodic. Some people with CIU may also have swelling of the skin.

##### What is IgE?

IgE is short for immunoglobulin E. This substance, which occurs naturally in your body in small amounts, plays an important role in allergic asthma and CIU.

If you have allergic asthma, your body makes more IgE when you breathe in an allergen that triggers your asthma. This can cause a series of chemical reactions known as the "allergic-inflammatory process in allergic asthma". It can result in 2 things:

- The muscles that surround your airways begin to tighten. This is known as *constriction of the airways*
- Your airways become irritated and swell up. This is known as *inflammation of the airways*

Together, constriction and inflammation of the airways make it harder for you to breathe. This can lead to an asthma attack, also known as exacerbation.

##### What is XOLAIR?

XOLAIR is supplied as a powder in a small glass vial. The powder is dissolved in sterile water for injection before it is injected. Each vial delivers 150 mg of omalizumab. XOLAIR is also available as a ready to use solution in a pre-filled syringe. The syringe is available in both 75 mg and 150 mg of omalizumab.

**Asthma and Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

XOLAIR blocks 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 significant role in causing asthma and CRSwNP. Your doctor will measure the amount of IgE with a blood test and determine your body weight before starting the treatment with XOLAIR. By blocking IgE, XOLAIR helps stop the allergic-inflammatory process in allergic asthma.

Adding XOLAIR injections to treatment with inhaled steroids has been clinically proven to help reduce the number of asthma attacks. XOLAIR has not been proven to work in other allergic conditions.

XOLAIR is not a rescue medicine and should not be used to treat sudden asthma attacks. It is not a substitute for the medicines you are already taking.

**Chronic Idiopathic Urticaria (CIU)**

XOLAIR blocks a substance called immunoglobulin E (also known simply as IgE) which is produced by your body. By binding to IgE, XOLAIR reduces the activation of certain cells in your body and the release of histamine and other chemicals. This helps reduce symptoms of CIU, including itching and hives.

**When it should not be used:**

You should not be given XOLAIR:

If you are hypersensitive (allergic) to omalizumab or any of the other ingredients of XOLAIR (see below), or if you have ever had an allergic reaction to a XOLAIR injection.

If you ever had an allergic reaction to latex (information specific to the needle cap of the pre-filled syringe).

***Use in children***

Allergic asthma: XOLAIR is not indicated for children below 6 years of age

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

XOLAIR is not indicated for children below 18 years of age.

Chronic idiopathic urticaria (CIU): XOLAIR is not indicated for children below 12 years of age

***Pregnancy***

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Before starting treatment with XOLAIR, tell your doctor if you are pregnant or think that you may be pregnant. Your doctor will discuss with you the benefits and potential risks of being given this medicine during pregnancy. Tell your doctor straight away if you become pregnant while being treated with XOLAIR.

***Breast-feeding***

Ask your doctor, nurse or pharmacist for advice before being given any medicine.

Tell your doctor if you are breast-feeding. It is not known whether omalizumab, the active substance of XOLAIR, passes into breast milk or in what ways this could affect the baby. Your doctor will discuss with you the benefits and potential risks of being given this medicine while you are breast-feeding.

***Fertility***

There are no human fertility data for XOLAIR.

***Driving and using machines***

You may experience dizziness, sleepiness or fatigue after receiving XOLAIR, in which case you should not drive or use machines.

**What the medicinal ingredient is:**

omalizumab

**What the nonmedicinal ingredients are:**

XOLAIR 75 mg and 150 mg solution for injection in pre-filled syringe: L-arginine hydrochloride, L-histidine hydrochloride, L histidine, polysorbate 20, water for injection.

XOLAIR 150 mg powder and solvent for solution for injection: histidine, histidine hydrochloride monohydrate, polysorbate 20 and sucrose

**What dosage forms it comes in:**

XOLAIR 75 mg and 150 mg solution for injection in pre-filled syringe and sterile powder for reconstitution, 150 mg vial (125 mg/mL after reconstitution)

**WARNINGS AND PRECAUTIONS**

1- A severe allergic reaction called anaphylaxis can happen in some patients after receiving XOLAIR. Anaphylaxis is a life-threatening condition. Signs and symptoms of anaphylaxis include difficulty breathing, light-headedness, rash, itching, and swelling of the tongue and throat (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

Anaphylaxis from XOLAIR can happen as early as after the first injection or hours later, and/or after any XOLAIR injection. Your healthcare professional should watch you for some time for signs and symptoms of anaphylaxis after treatment is initiated. If you have any of the signs or symptoms of anaphylaxis, tell your doctor or nurse immediately, and get emergency medical treatment right away.

Your healthcare professional should instruct you about starting emergency medical treatment and getting further medical care if you have any signs or symptoms of anaphylaxis.

2- Weakness or paralysis of limbs or face, loss of sensation, difficulty speaking or understanding, transient loss of vision in one eye could be symptoms of a transient ischemic attack or stroke. Seek immediate medical attention if you experience any such symptoms.

BEFORE you use XOLAIR, talk to your doctor or

pharmacist if you have:

- Hypersensitivity reaction to any drug (Warnings and Precautions)
- Any other known hypersensitivity (Warnings and Precautions)
- Any allergies to this drug or its ingredients or components of the container (Contraindications)
- If you ever had an allergic reaction to latex (information specific to the needle cap of the pre-filled syringe).

#### *Parasite infections*

If you are living in a region where parasite infections are frequent or traveling to such a region, please tell your doctor. XOLAIR may weaken your resistance to such infections.

If you are taking a treatment against parasite infection, please tell your doctor. XOLAIR may reduce the efficacy of your treatment.

### INTERACTIONS WITH THIS MEDICATION

Please inform your doctor or nurse if you are taking or have recently taken any other medicines, even those not prescribed. Never suddenly stop taking, or change the dose of, your inhaled steroids or any other asthma medicine or of current medicine for CIU you are taking unless your doctor tells you to do so.

XOLAIR can be used together with other medicines for asthma and/or CRSwNP, as well as with H1 or H2 antihistamines and leukotriene receptor antagonists (LTRAs) for CIU, but it is still important to tell your doctor that you are taking them before you are given XOLAIR.

### PROPER USE OF THIS MEDICATION

XOLAIR is used as an injection under your skin (known as a subcutaneous injection).

The injection using the powder for solution for injection formulation is only supposed to be given by a healthcare professional.

#### Injecting XOLAIR pre-filled syringe

- You and your doctor will decide if you should inject XOLAIR yourself. The first 3 doses are given by or under the supervision of a healthcare professional. (see WARNINGS AND PRECAUTIONS)
- 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 XOLAIR injection after he or she has received proper training.

For detailed instructions on how to inject XOLAIR, see “Instructions for use of XOLAIR pre-filled syringe” at the end of this leaflet.

#### Training to recognize serious allergic reactions

It is also important that you do not inject XOLAIR yourself until you have been trained by your healthcare professional 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 SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

A patient support program has been established to provide you with injection services. Contact your doctor to enroll.

#### Asthma

Based on your dose, your doctor will also tell you if you will need 1, 2, or 3 injections per dose. If you need more than 1 injection per dose, each will be given in a different area of your body.

You will receive 75, 150, 225 or 300 mg every four weeks, or 225, 300 or 375 mg every two weeks. You will probably need to continue taking your current asthma medicine during XOLAIR treatment but after 16 weeks you may be able to reduce or stop any other asthma medication that you are taking. Your doctor will discuss this with you. You should not reduce the dose of other asthma medication without first discussing with your doctor, even if you are feeling better.

#### Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

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 CRSwNP medicine during XOLAIR treatment. Do not stop taking any CRSwNP medications without talking to your doctor.

#### Chronic Idiopathic Urticaria (CIU)

XOLAIR 150 mg or 300 mg are administered subcutaneously every 4 weeks. The efficacy of XOLAIR in CIU patients depends on the quantity that is injected.

#### Usual dose:

#### Asthma and Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

XOLAIR is given once every 2 or 4 weeks. Your dose will be determined by your body weight and your IgE level, which your doctor will measure with a simple blood test. Based on your dose, your doctor will also tell you if you will need 1, 2, 3 or 4 injections per dose. If you need more than 1 injection, each will be given in a different place on your body.

Because it is a controller or *maintenance medicine*, you will receive XOLAIR on a regular schedule. It is important that you continue to receive your XOLAIR injections even when you are feeling well.

#### Chronic Idiopathic Urticaria (CIU)

You will be given 1 or 2 injections at a time every 4 weeks.

Continue taking your current medicine for CIU during XOLAIR treatment. Do not stop taking any medicine without talking to your doctor first.

Continue to use XOLAIR for as long as your doctor tells you to do so.

If you have questions about how long to receive XOLAIR, talk to your doctor or your pharmacist.

**Overdose:**

The maximum tolerated dose of XOLAIR has not been determined. Single intravenous doses up to 4000 mg have been administered to patients without evidence of dose-limiting toxicities. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

If you think you have taken too much XOLAIR, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Take special care if you have a disorder where your own immune system attacks part of your own body (autoimmune disease).

A specific type of allergic reaction (serum sickness) has also been observed in patients treated with XOLAIR or similar products. Signs include joint pain, stiffness, rash, fever, swollen/enlarged lymph nodes and occur typically within one to five days after the injection. If you have such a reaction after taking XOLAIR, contact a doctor immediately.

In initial clinical studies in asthma, the number of observed malignancies was uncommon (<1%) in all studied patients who received XOLAIR or a placebo injection containing no medication, with 0.5% reported in patients receiving XOLAIR and 0.2% in patients receiving placebo injections. Results from a review of all the clinical trials now completed (double in size from the initial studies) and also results from a 5 year observational study found that XOLAIR was not associated with an increased risk of malignancy. Please discuss this information with your doctor.

The most common side effects reported in patients who received XOLAIR in clinical studies in asthma and CIU are listed below. This is not a complete list of all side effects reported with XOLAIR.

- Injection-site reaction (bruising, redness, warmth, burning, stinging, or other discomfort around the injection site)
- Viral infections
- Upper respiratory tract infection
- Sinusitis
- Headache
- Sore throat
- Urinary tract infection
- Feeling dizzy
- Abdominal pain

In children 6 to less than 12 years of age with asthma:

- Common cold symptoms
- Headache
- Fever
- Sore throat
- Pain or discomfort of your ear
- Nausea
- Vomiting
- Nose bleeding

Other less commonly observed side effects included pain, broken bones, leg pain, joint pain, muscle pain, joint swelling, and hair loss.

If you notice hives, skin rash, injection site reactions or any side effects not mentioned in this leaflet, please inform your doctor or nurse.

If you experience any of these, tell your doctor straight away.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

As with all medicines, patients treated with XOLAIR can experience side effects.

The side effects caused by XOLAIR are usually mild. In clinical studies, they were about as common in people who were given XOLAIR as those who were given a placebo (or dummy) injection that did not contain omalizumab.

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

XOLAIR can potentially cause serious side effects. You must look out for signs of these conditions while you use XOLAIR. Some patients had a serious allergic reaction called anaphylaxis, occurring at an average of 2 out of 1000 patients (0.2%) or more. Should it happen, anaphylaxis quickly causes symptoms such as rash, itching, and swelling of the tongue and throat, which can make it hard to breathe and can be life threatening. Seek medical help immediately if you notice any signs indicating a severe allergic reaction or other serious side effects. Such signs are in the “SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM” table below. Please speak with your doctor about this information.

It is important that you receive training from your healthcare professional in how to recognize early signs of severe allergic reactions, and how to manage these reactions if they occur (see PROPER USE OF THIS MEDICATION). The majority of severe allergic reactions occur within the first 3 doses of XOLAIR.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Rare Sudden severe allergic reaction (sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, fast heartbeat, dizziness and light headedness, shortness of breath, wheezing or trouble breathing)			√
Rare Low blood platelet count with symptoms such as bleeding or bruising more easily than normal			√
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			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**HOW TO STORE IT**

XOLAIR is to be stored in a refrigerator (2°-8°C). Do not freeze. In order to protect from light, store in the original package. Any unused product or waste material should be disposed of in accordance with local requirements. Your doctor or nurse will know this. Keep this medicine out of the sight and reach of children. Do not shake.

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program Health Canada, Postal Locator 0701E Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: [www.Novartis.ca](http://www.Novartis.ca) or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883 or by contacting the patient support program at 1-866-996-5247

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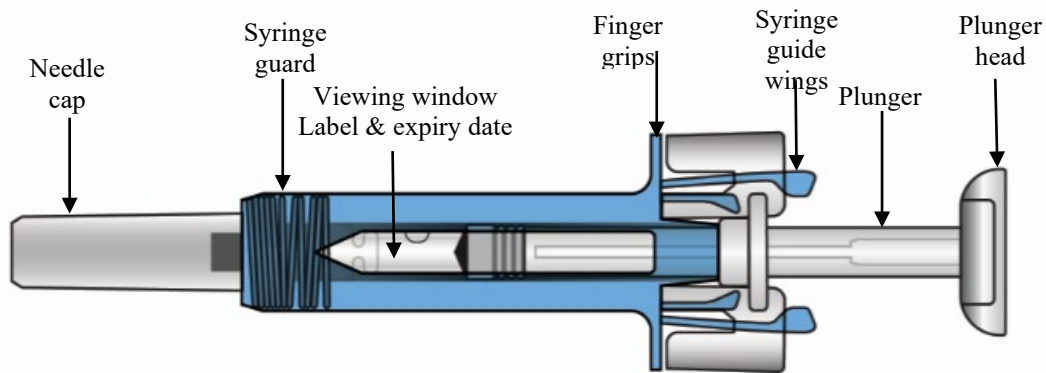
XOLAIR is a registered trademark.

## Instructions for use - XOLAIR solution for injection in pre-filled syringe

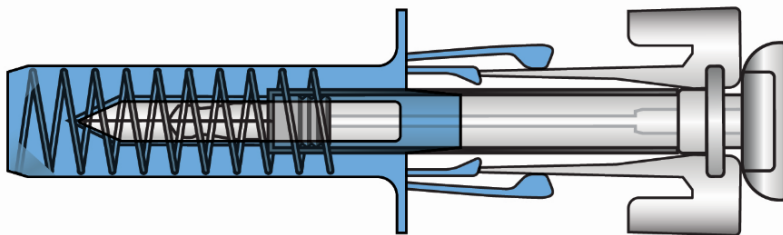
Read ALL the way through these instructions before injecting. If your doctor decides that you or a caregiver may be able to give your injections of XOLAIR at home, you need to be trained by your healthcare professional before you inject yourself or others. Children (6 to less than 12 years of age) are not expected to inject XOLAIR themselves, however, if deemed appropriate by their doctor, a caregiver may give them their XOLAIR injection after proper training. The box contains XOLAIR pre-filled syringe(s) individually sealed in a plastic tray.

XOLAIR pre-filled syringe is available in two strengths, 75 mg and 150 mg. You may receive one or both strengths from the pharmacy.

### Your XOLAIR 75 mg pre-filled syringe before use (blue)

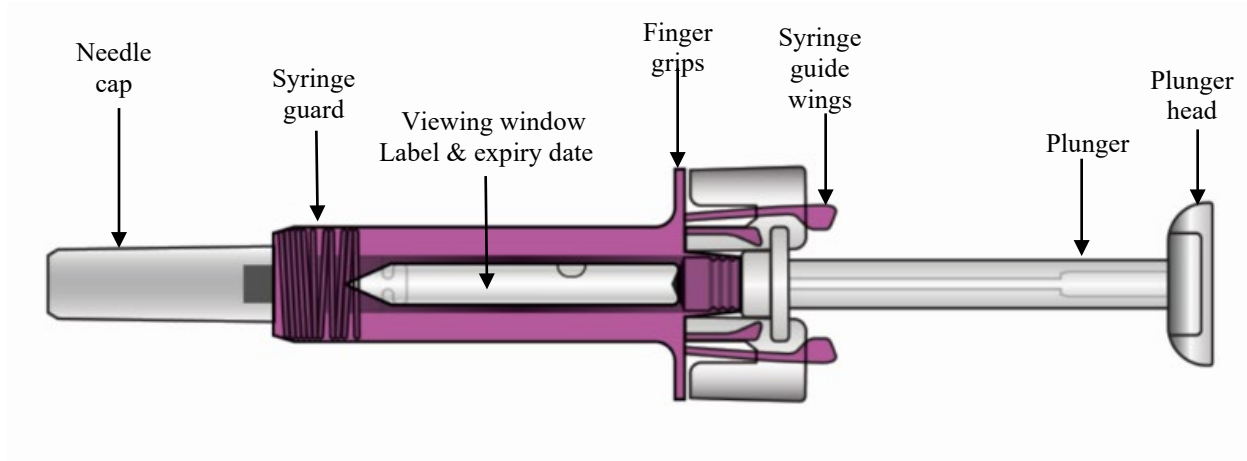


### Your XOLAIR 75 mg pre-filled syringe after use (blue)

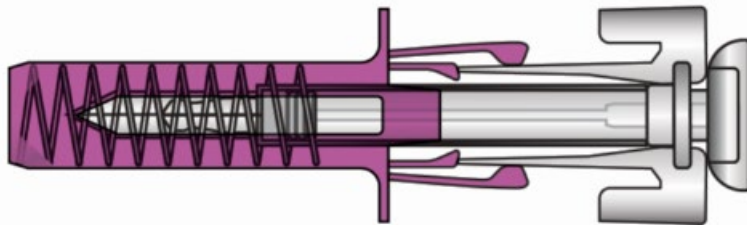


After the medicine has been injected the syringe guard will be activated to cover the needle. This is intended to protect against accidental needle stick injuries.

**Your XOLAIR 150 mg pre-filled syringe before use (purple)**



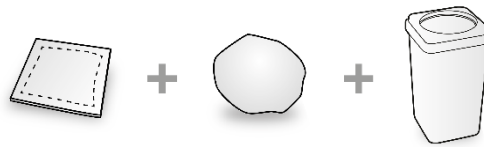
**Your XOLAIR 150 mg pre-filled syringe after use (purple)**



After the medicine has been injected the syringe guard will be activated to cover the needle. This is intended to protect against accidental needle stick injuries.

**Other items you need for your injection:**

- Alcohol swab.
- Cotton ball or gauze.
- Sharps disposal container.



**Important safety information**

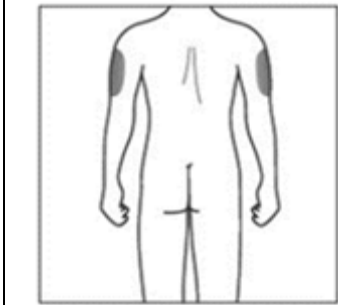
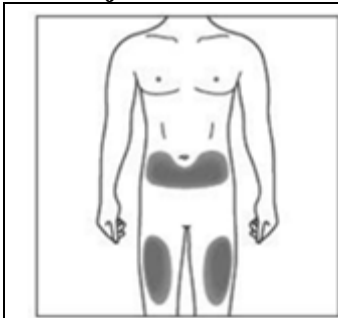
**Caution: Keep the syringe out of the sight and reach of children.**

- The needle cap of the syringe may contain dry rubber (latex), which should not be handled by anyone who is sensitive to this substance.
- Do not open the sealed outer box until you are ready to use this medicine.
- Do not use this medicine if either the seal on the outer box or the seal of the plastic tray is broken, as it may not be safe for you to use.
- Never leave the syringe where others might tamper with it.
- Do not shake the syringe.
- Be careful not to touch the syringe guard wings before use. If the wings are touched, the syringe guard may be activated too early.
- Do not remove the needle cap until just before you give the injection.
- The syringe cannot be re-used. Dispose of the used syringe immediately after use in a sharps container.

### Storage of the XOLAIR pre-filled syringe

- 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.
- Remember to take the syringe out of the refrigerator and allow it to reach room temperature (25°C) before preparing it for injection (about 20 minutes). Leave the syringe in the box to protect it from light. The time that the syringe is kept at room temperature (25°C) before use must not exceed 4 hours.
- 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.

### The injection site











The injection site is the place on the body where you are going to use the syringe.

- The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 5 centimetres around the navel (belly button).
- If you need to give more than one injection for the full dose, choose a different injection site each time you inject.
- Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks. If a caregiver is giving the injection, the outer upper arms may also be used. Do not try to inject into the upper arm area by yourself.



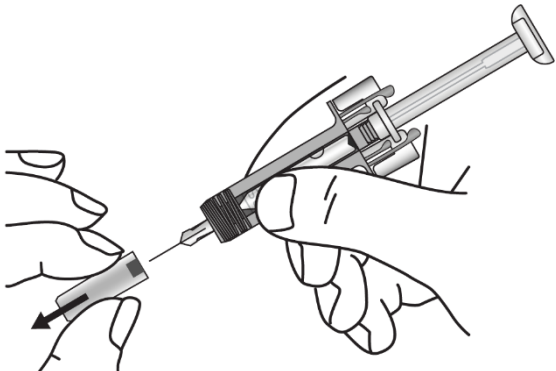
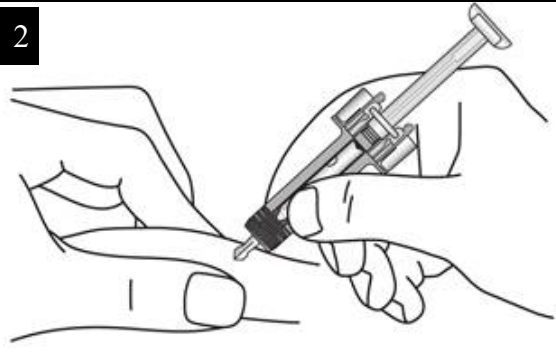
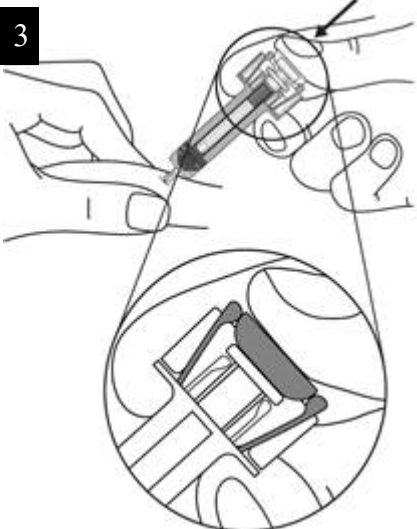
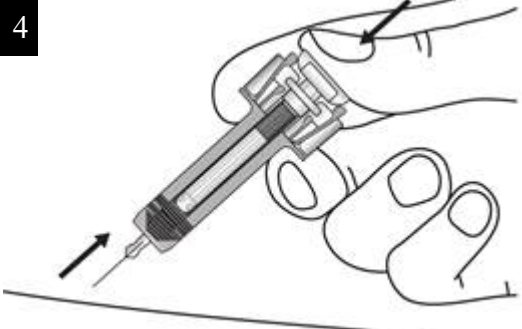
**Preparing the XOLAIR pre-filled syringe for use**

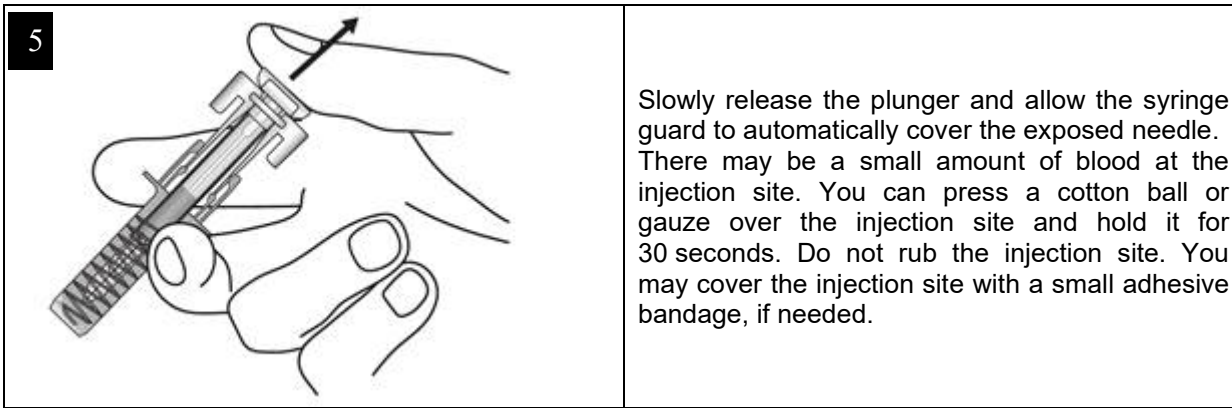
Note: XOLAIR pre-filled syringes are available in 2 dose strengths. Depending on the dose prescribed to you by your doctor, you may need to prepare one or more pre-filled syringes, and inject the contents of them all. The following table gives examples of how many injections of each dose strength you need for a given dose:

Dose	Syringes needed for the dose	
75 mg	1 blue (75 mg) 	
150 mg	1 purple (150 mg) 	
225 mg	1 blue (75 mg) + 1 purple (150 mg)	
300 mg	2 purple (150 mg) 	
375 mg	1 blue (75 mg) + 2 purple (150 mg)	
450 mg	3 purple (150 mg) 	
525 mg	1 blue (75 mg) + 3 purple (150 mg)	
600 mg	4 purple (150 mg) 	

1. Take the box containing the syringe out of the refrigerator and leave it **unopened** for about 20 minutes so that it reaches room temperature (leave the syringe in the box to protect it from light).
2. When you are ready to use the syringe, wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.
4. Remove the plastic tray from the box and peel back the paper cover. Gripping the middle of the syringe guard, lift the syringe out of the tray.
5. Inspect the syringe. The liquid should be clear to slightly cloudy. Its color may vary from colorless to pale brownish-yellow. You may see an air bubble, which is normal. **DO NOT USE** if the syringe is broken or if the liquid looks distinctly cloudy or distinctly brown, or contains particles. In all these cases, return the entire pack to the pharmacy.
6. Holding the syringe horizontally, look into the viewing window to check the expiry date printed on the label. Note: It is possible to rotate the inner part of the syringe assembly so that the label can be read in the viewing window. **DO NOT USE** if the product has expired. If expired, return the entire pack to the pharmacy.

**How to use the XOLAIR pre-filled syringe**

<p><b>1</b></p> 	<p>Carefully remove the needle cap from the syringe. Discard the needle cap. You may see a drop of liquid at the end of the needle. This is normal.</p>
<p><b>2</b></p> 	<p>Gently pinch the skin at the injection site and insert the needle as shown. Push the needle all the way in to ensure that the medicine can be fully administered.</p>
<p><b>3</b></p> 	<p>Hold the syringe as shown. <b>Slowly</b> depress the plunger <b>as far as it will go</b> so that the plunger head is completely between the syringe guard wings.</p>
<p><b>4</b></p> 	<p><b>Keep the plunger fully depressed</b> while you carefully lift the needle straight out from the injection site.</p>



### If your prescribed dose requires more than 1 injection:

- Throw away the used pre-filled syringe as described in the disposal instructions below.
- Repeat the preparation and injection steps for the next injection using a new pre-filled syringe.
- Choose a different injection site for each new injection at least 2.5 cm from other injection sites.
- Complete all the required injections for your prescribed dose, immediately one after another. Contact your healthcare provider if you have any questions.

### Disposal instructions

