

# XOLAIR®

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

## What is in this leaflet

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## What Xolair is used for

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

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

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

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

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

### **Chronic rhinosinusitis with nasal polyps (CRSwNP)**

Xolair is used to treat CRSwNP in adults (18 years of age and older) 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 Spontaneous Urticaria (CSU)**

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

## How it works

### **Allergic Asthma and CRSwNP**

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

### **Chronic Spontaneous Urticaria (CSU)**

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

## Before you use Xolair

### **-When you must not use it**

If you are allergic to Xolair or any of the ingredients of Xolair listed at the end of this leaflet.

If you think you may be allergic, ask your doctor for advice.

### **- Before you start to use it**

### **Warnings and precautions**

Tell your doctor before you use Xolair:

- If you have kidney or liver problems.
- If you have a disorder where your own immune system attacks parts of

your own body (autoimmune disease).

- If you live in a region where parasite infections are frequent or traveling to such a region, Xolair may weaken your resistance to such infections.
- If you have had a previous severe allergic reaction (anaphylaxis) resulting, for example, from a medicine, an insect bite or food.
- If you have ever had an allergic reaction to latex. The needle cap of the pre-filled syringe may contain dry rubber (latex).

### ***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. Seek medical help immediately if you notice any signs indicating a severe allergic reaction or other serious side effects. Such signs are listed under sub-section "Some side effects can be serious" in section Side effect.

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

## Children and adolescents

### **Allergic Asthma**

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

### **CRSwNP**

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

### **Chronic Spontaneous Urticaria**

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

### ***Older people (65 years or above)***

Xolair may be given to people aged 65 years and over. There is no evidence to suggest that any special precautions are needed when older people are treated, although experience is still limited.

### ***Pregnancy***

If you are pregnant or plan to become pregnant, tell your doctor before starting treatment with Xolair. Your doctor will discuss with you the benefits and potential risks of using this medicine during pregnancy.

If you become pregnant while being treated with Xolair, tell your doctor straight away.

### ***Breast-feeding***

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

### ***Taking other medicines***

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

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

### ***How to use Xolair***

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

#### ***- How much to use***

#### **Allergic Asthma and CRSwNP**

Your doctor will decide how much Xolair you need and how often you will need it. This depends on your body weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in your blood. You will need 1 to 4 injections at a time. You will need the injections either every two weeks or every four weeks as prescribed by your doctor.

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

#### **Chronic Spontaneous Urticaria**

You will need 1 or 2 injections at a time every four weeks.

Keep taking your current medicine for CSU during Xolair treatment. Do not stop taking any medicine without talking to your doctor.

#### ***- When to use it***

#### **Allergic Asthma and CRSwNP**

You will need the injections either every two weeks or every four weeks as prescribed by your doctor.

#### **Chronic Spontaneous Urticaria**

You will need 1 or 2 injections at a time every four weeks.

#### ***- How long to use it***

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

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

#### **Allergic Asthma and CRSwNP**

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

#### ***- If you forget to use it***

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

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

#### ***- If you use too much (overdose)***

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

### ***While you are using it***

#### ***- Things you must do***

#### **How Xolair is used**

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

### **Injecting Xolair**

- You and your doctor will decide if you should inject Xolair yourself. The first 3 doses should be given by or under the supervision of a healthcare professional (see Section 'Before you use Xolair').
- 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' 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 doctor or nurse on:

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

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

#### ***- Things you must not do***

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

#### ***- Things to be careful of***

#### **If you stop using Xolair**

Interrupting or ending the treatment with Xolair may lead to recurrence of your symptoms.

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

### **Side effects**

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

**Some side effects can be serious**  
**Seek medical attention immediately if you notice any signs of the following side effects:**

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

Xolair contains a protein, and as with any protein, local or systemic allergic reactions may potentially occur. Sudden severe allergic reactions have been rarely reported. If you notice sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue, larynx (voice box), windpipe or other parts of the body, fast heartbeat, dizziness and light headedness, shortness of breath, wheezing or trouble breathing, tell your doctor immediately.

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

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

#### **Other possible side effects**

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

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

- fever (in children)

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

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

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

- feeling sleepy or tired
- tingling or numbness of the hands or feet
- fainting, postural hypotension (low blood pressure while sitting or standing), flushing
- sore throat, coughing, acute breathing problems
- nausea, diarrhea, indigestion
- itching, hives, rash, increased sensitivity of the skin to sun
- weight increase
- flu-like symptoms
- swelling arms

**Rare:** *may affect up to 1 in every 1000 people*

- parasite infections

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

- joint swelling
- hair loss

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

You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by visiting the website [npa.gov.my](http://npa.gov.my) [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

#### **Storage and Disposal of Xolair**

##### - Storage

- Do not use after the expiry date shown on the box
- Store at 2°C–8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light.
- Keep out of the sight and reach of children.

##### - Disposal

Ask your pharmacist how to dispose of medicines you no longer use.

#### **Product Description**

##### - What it looks like

##### **Solution for injection in pre-filled syringe**

Xolair 75 mg comes as a clear to slightly opalescent, colorless to pale brownish-yellow solution for injection in a pre-filled syringe. Each pre-filled syringe of 0.5 mL contains 75 mg of omalizumab. Xolair 150 mg comes as a clear to slightly opalescent, colorless to pale brownish-yellow solution for injection in a pre-filled syringe. Each pre-filled syringe of 1 mL contains 150 mg of omalizumab.

Xolair is available in packs with 1 pre-filled syringe of either 0.5 mL (75 mg) or 1 mL (150 mg) solution for injection. This information might differ in some countries.

##### - Ingredients

- The **active substance** of Xolair is omalizumab
- The **other ingredients** are: L-arginine hydrochloride, L-histidine hydrochloride, L-histidine, polysorbate 20, water for injection (for the needle cap of Xolair pre-filled syringe, see section ‘Before you use Xolair’ and ‘Instructions for use’ for further information on latex).

This information might differ in some countries

- MAL number:

Xolair 75mg/0.5ml Solution for Injection  
in Pre-filled Syringe:

MAL22086008ACRZ

Xolair 150mg/ml Solution for Injection  
in Pre-filled Syringe:

MAL22086007ACRZ

**Manufacturer**

Vetter Pharma-Fertigung GmbH & Co.  
KG

Eisenbahnstrasse 2 – 4,  
D-88085 Langenargen,  
Germany.

**Product Registration Holder**

Novartis Corporation (Malaysia) Sdn.  
Bhd.

Level 18, Imazium,  
No.8, Jalan SS21/37, Damansara  
Uptown,

47400 Petaling Jaya.

**Date of revision**

Aug 2025 (Information issued on Jun  
2023)

**Serial Number**

NPRA (R3) 21/18

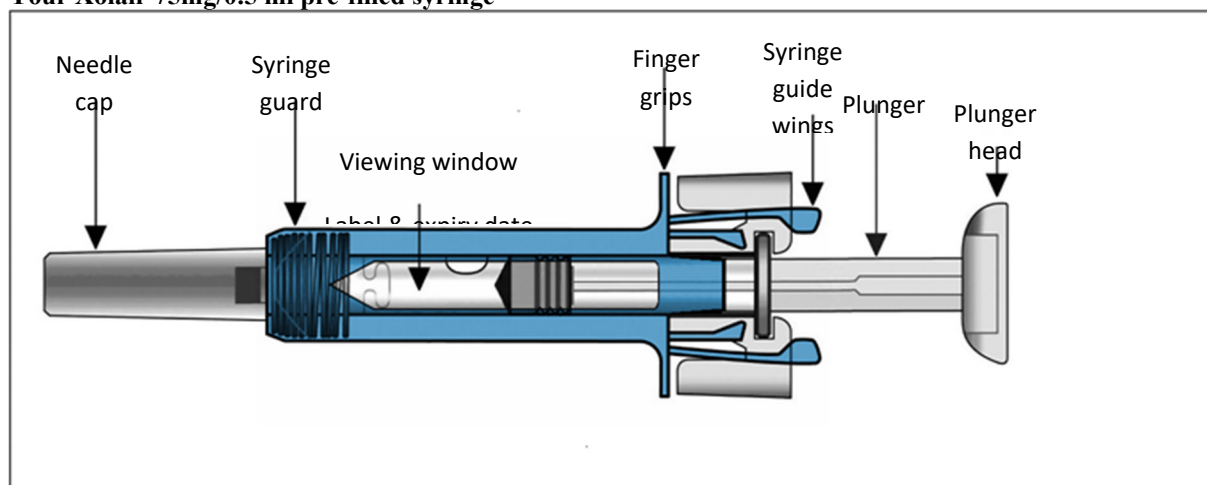
**Instructions for Use**

**Xolair solution for injection in pre-filled syringe (pre-filled syringe with 26-gauge staked needle)**

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 doctor, nurse or pharmacist 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.

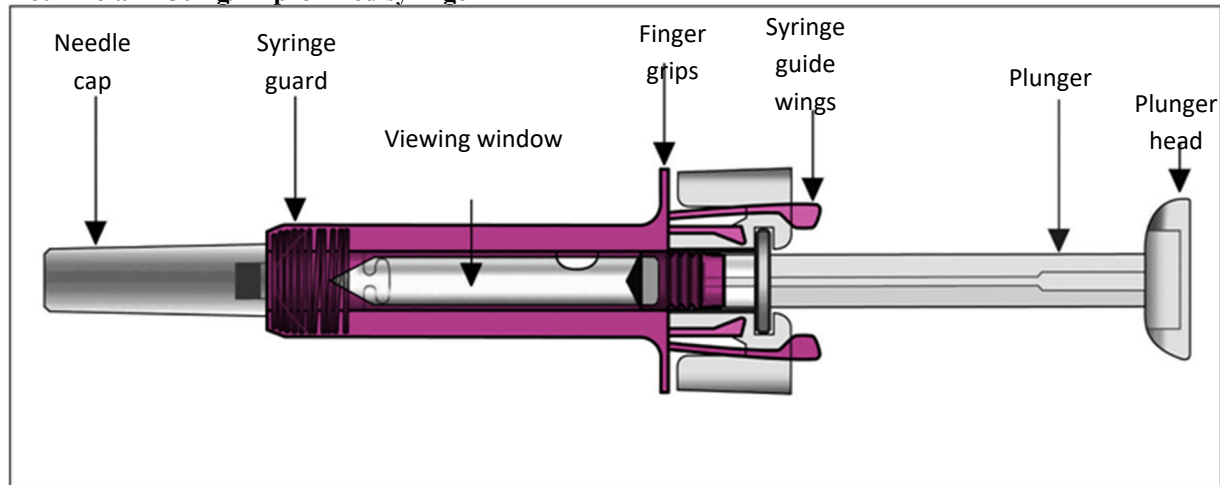
Xolair pre-filled syringe is available in two strengths, 75 mg and 150 mg. You may receive one or both strengths from the pharmacy.

**Your Xolair 75mg/0.5 ml pre-filled syringe**



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.

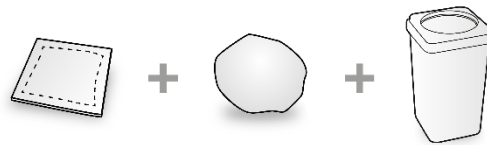
### Your Xolair 150mg/ml pre-filled syringe



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

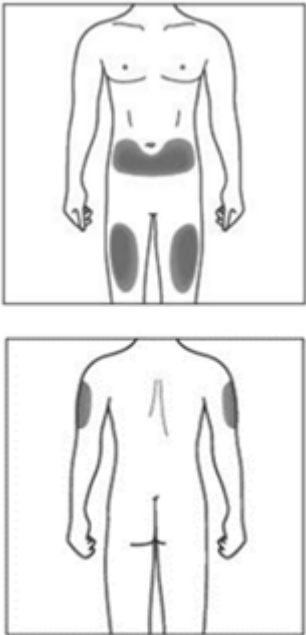
#### Caution: Keep the syringe out of the sight and reach of children.

- 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.
- Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap.
- 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 30 minutes). Leave the syringe in the box to protect it from light. If necessary, the product may be returned to the refrigerator for later use. The total time that the syringe is kept at room temperature (25°C) before use must not exceed 48 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.

### Preparing the Xolair pre-filled syringe for use

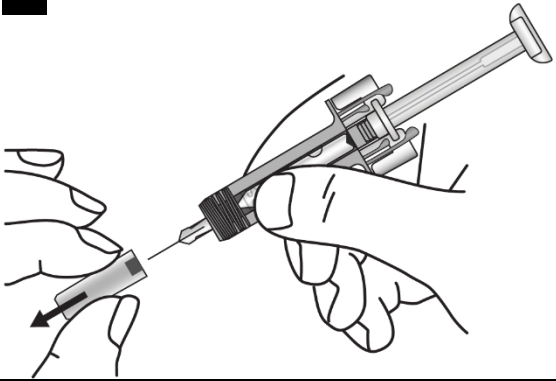
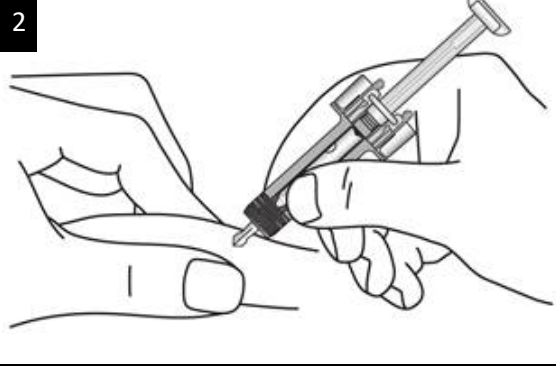
Note: Depending on the dose prescribed to you by your doctor, you may need to prepare one or more pre-filled syringes, and inject the contents of them all. The following table gives examples of how many injections of each dose strength you need for a given dose:

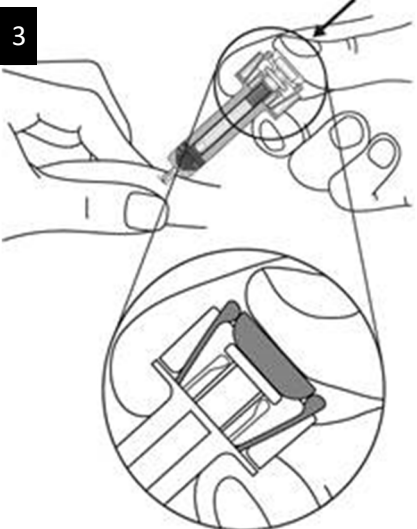
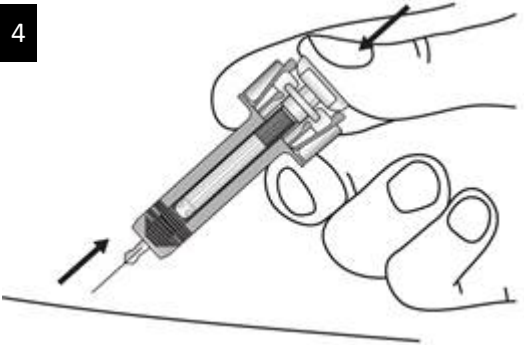
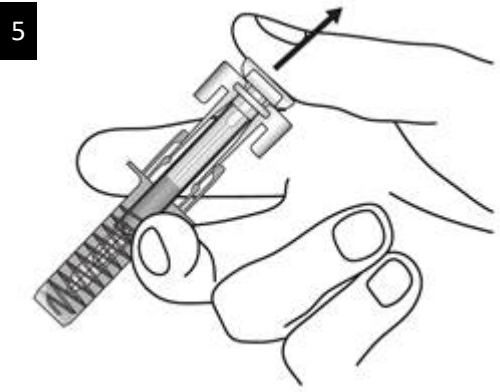
| Dose   |                | Syringes needed for the dose |                                                                                                                                                                          |
|--------|----------------|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 30 minutes so that it reaches room temperature (leave the syringe in the box to protect it from light).

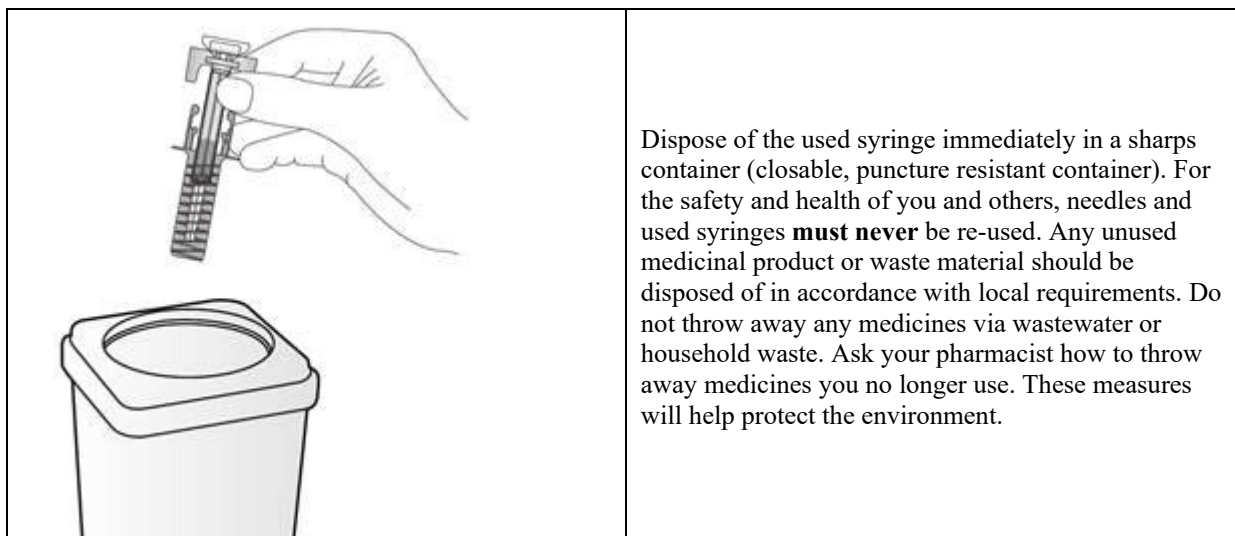
2. When you are ready to use the syringe, wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.
4. Remove the plastic tray from the box and peel back the paper cover. Gripping the middle of the syringe guard, lift the syringe out of the tray.
5. Inspect the 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

|                                                                                                                                |                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div data-bbox="121 877 167 934">1</div>     | <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>                  |
| <div data-bbox="121 1310 167 1367">2</div>  | <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>3</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>4</p>   | <p><b>Keep the plunger fully depressed</b> while you carefully lift the needle straight out from the injection site.</p>                                                                                                                                                                                                                                                |
| <p>5</p>  | <p>Slowly release the plunger and allow the syringe guard to automatically cover the exposed needle. There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 30 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.</p> |

#### Disposal instructions



Dispose of the used syringe immediately in a sharps container (closable, puncture resistant container). 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.