

SCHEDULING STATUS

S4

Xolair® 75 mg/0,5 mL and 150 mg/1,0 mL solution for injection in pre-filled syringe

Sugar free

Omalizumab, 75 mg and 150 mg

Read all of this leaflet carefully before you start using XOLAIR®

- Read all of this leaflet carefully before you start using XOLAIR
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- XOLAIR has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

XOLAIR SHOULD ALWAYS BE INJECTED IN YOUR DOCTOR'S ROOMS.

XOLAIR® solution for injection in pre-filled syringe and pre-filled pen:

- Read section 3 'How to use XOLAIR' carefully and follow the 'Instructions for use and handling'.

What is in this leaflet

1. What XOLAIR is and what it is used for.
2. What you need to know before you use XOLAIR.
3. How to use XOLAIR.

4. Possible side effects.
5. How to store XOLAIR.
6. Contents of the pack and other information.

1. What XOLAIR is and what it is used for

What XOLAIR is:

Omalizumab is a man-made protein that is similar to natural proteins produced by the body. It belongs to a class of medicines called monoclonal antibodies.

XOLAIR® solution for injection in pre-filled syringe or pre-filled pen:

Each pre-filled syringe of 0.5 mL contains 75 mg of omalizumab.

Each pre-filled syringe of 1 mL contains 150 mg of omalizumab.

What XOLAIR is used for:

Allergic Asthma

XOLAIR is indicated for the prevention of asthma exacerbations and control of asthma symptoms, when given as add-on therapy for patients with severe persistent allergic asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and who have reduced lung function (FEV1 < 80 %), as well as 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.

Children (6 to < 12 years of age):

XOLAIR is indicated as add-on therapy to reduce the dose of inhaled corticosteroids in patients 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.

XOLAIR treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma.

XOLAIR works by blocking a substance called immunoglobulin E (IgE) which is produced by your body. IgE plays a key role in causing allergic asthma.

Chronic Spontaneous Urticaria (CSU)

XOLAIR is used to treat Chronic Spontaneous Urticaria in adults and adolescents (12 years of age and older) whose CSU symptoms are not well controlled by the medicines usually used to treat the condition, such as antihistamines and leukotriene receptor antagonists (LTRAs).

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.

Nasal Polyps:

This medicine is used to treat nasal polyps in adults (18 years of age and older) who are already receiving intranasal corticosteroids (corticosteroid nasal spray), but whose symptoms are not well controlled by these medicines. Nasal polyps are small growths on the lining of the nose. XOLAIR helps to reduce the size of the polyps and improves symptoms including nasal congestion, loss of sense of smell, mucus in the back of the throat and runny nose.

Xolair works by blocking a substance called immunoglobulin E (IgE), which is produced by the body. IgE contributes to a type of inflammation that plays a key role in causing allergic asthma and nasal polyps.

2. What you need to know before you use XOLAIR

Do not use XOLAIR:

- If you are allergic to any of the ingredients in XOLAIR. The ingredients are listed at the beginning of this leaflet.
- If you think you may be allergic to any of the ingredients, tell your doctor since you should not be given XOLAIR.

Warnings and precautions**Tell your doctor or health care provider before being given the injection:**

- 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 infections caused by parasites are common or if you are travelling to such a region as XOLAIR may weaken your resistance to such infections;
- if you have ever had an allergic reaction to latex. The needle cap of the syringe may contain dry rubber (latex).

XOLAIR contains a protein, and proteins can cause serious allergic reactions in some people.

- Signs include rash, difficulty in breathing, swelling or feeling faint. If you have an allergic reaction after taking XOLAIR, contact a doctor as soon as you can.
- XOLAIR is not meant to prevent or treat other allergy-type conditions, such as sudden allergic reactions, hyperimmunoglobulin E syndrome (an inherited immune disorder), aspergillosis (a fungus-related lung disease), food allergy, allergic skin rash or hay fever.

Allergic Asthma

- You should not receive XOLAIR to treat acute asthma symptoms, like a sudden asthma attack.

- You will have been given a separate medicine for this.

Children (under 6 years of age):

Allergic Asthma

- Do not give XOLAIR to children under 6 years of age. There are not enough data in this group.

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.

Other medicines and XOLAIR

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Medicines to treat an infection caused by a parasite, as XOLAIR may reduce the effect of your medicines.
- Although XOLAIR can be used together with inhaled corticosteroids and other medicines for allergic asthma as well as with H1 or H2 antihistamines and LTRAs for chronic spontaneous urticaria, it is still important to tell your doctor that you are taking these medicines.

Pregnancy, breastfeeding and fertility

Pregnancy

- If you are pregnant or breastfeeding your baby while using this medicine, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
- You should not use XOLAIR when you are pregnant.
- If you plan to become pregnant, tell your doctor before starting treatment with XOLAIR.
- Your doctor will discuss with you the benefits and potential risks of being given this medicine during pregnancy.
- If you become pregnant while being treated with XOLAIR, tell your doctor immediately.

Breastfeeding

- You should not use XOLAIR when you are breastfeeding.

Driving and using machinery

XOLAIR may make you feel sleepy, faint or dizzy and affect your mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment (see 4 *Possible side effects*). If this happens to you do not drive or use machines.

3. How to use XOLAIR

Do not share medicines prescribed for you with any other person.

Always use XOLAIR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

XOLAIR is given to you by a doctor or nurse as an injection just under the skin.

Allergic Asthma

- Your doctor will work out how much XOLAIR you need and how often you will be given it.
- This depends on your body weight and the results of a blood test carried out before start of the treatment to measure the amount of IgE in your blood.
- Follow carefully all instructions given by your doctor or nurse.

How much you will be given

Allergic Asthma

- You will be given 1 to 4 injections at a time, either every two weeks or every four weeks.
- Carry on taking your current asthma medicine during XOLAIR treatment.
- Do not stop taking any asthma medicines without talking to your doctor.
- You may not see an immediate improvement in your asthma after beginning XOLAIR therapy.
- It usually takes several weeks to have the full effect.

Chronic Spontaneous Urticaria

- You will be given 1 or 2 injections at a time every four weeks.
- Continue taking your current medicine for CSU during XOLAIR treatment.
- Do not stop taking any medicine without talking to your doctor first.

Nasal Polyps

- 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.
- Keep taking your current nasal polyps medicine during XOLAIR treatment.
- Do not stop taking any nasal polyps medicine without talking to your doctor.

- You may not see an immediate improvement after beginning XOLAIR treatment.
- In patients with nasal polyps effects have been seen 4 weeks after the start of the treatment.

Use in children and adolescents

Nasal Polyps

XOLAIR should not be used in children and adolescents under 18 years of age.

Injecting XOLAIR pre-filled syringe:

- You and your doctor will decide if you should inject XOLAIR yourself.
- The first 3 doses are always given by or under the supervision of a healthcare professional.
- 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” or “Instructions for use of Xolair pre-filled pen” at the end of this leaflet.

Your doctor will tell you how long your treatment with XOLAIR will last.

If you have the impression that the effect of XOLAIR is too strong or too weak, tell your doctor or pharmacist.

If you use more XOLAIR than you should

- Since a healthcare professional will administer XOLAIR, he/she will control the dosage.
- In the event of overdosage, consult your doctor or pharmacist.
- If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of XOLAIR

Contact your doctor or hospital as soon as possible to re-schedule your appointment.

Do not use a double dose to make up for forgotten individual doses.

If you stop using XOLAIR

Interrupting or stopping the treatment with XOLAIR may cause your asthma or CSU symptoms or nasal polyps to come back.

4. Possible side effects

XOLAIR can have side effects. Some side effects can be serious.

Not all side effects reported for XOLAIR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking XOLAIR and tell your doctor immediately or go to the casualty department at your nearest hospital:

Serious side effects include:

Less Frequent side effects

Sudden severe allergic reactions: If you notice 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, or any other new symptoms, tell your doctor or nurse immediately.

If you have a history of severe allergic reactions (anaphylaxis) unrelated to XOLAIR, you may be more at risk of developing a severe allergic reaction following XOLAIR administration.

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to XOLAIR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- fever (in children);
- 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);
- 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 muscles and/or bones and/or joints (musculoskeletal pain, myalgia, arthralgia).

The following side effects have been reported less frequently:

- feeling dizzy, 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, diarrhoea, indigestion;
- itching, hives, rash, increased sensitivity of the skin to sun;
- weight increase;
- flu-like symptoms;
- joint swelling ;
- hair loss;
- parasitic infection.

The following side effects have been reported but the frequency is unknown:

- development of any combination of the following symptoms: pain, numbness, tingling in arms and legs, lumps or raised patches in the skin, worsening problems with breathing, nasal congestion (signs of so-called “Churg-Strauss syndrome”);
- low blood platelet count with symptoms such as bleeding or bruising more easily than normal;
- development of any of the following symptoms, especially if in combination: joint pain with or without swelling, rash, fever, swollen lymph nodes, muscle pain (signs of serum sickness).

If any of these side effects gets serious, or if you notice any side effect not mentioned in this leaflet please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety

APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of XOLAIR.

5. How to store XOLAIR

- Store all medicines out of reach of children.
- 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 (it will take 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 2 days (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.
- Do not store in a bathroom.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What XOLAIR contains:

Solution for injection in pre-filled syringe

The active substance of XOLAIR is: omalizumab.

The other ingredients of XOLAIR pre-filled syringe are: L-arginine hydrochloride, L-histidine hydrochloride, L-histidine, polysorbate 20, water for injection.

Solution for injection in pre-filled pen

The active substance of XOLAIR is: omalizumab.

The other ingredients of XOLAIR pre-filled syringe are: L-arginine hydrochloride, L-histidine hydrochloride, L-histidine, polysorbate 20, water for injection.

What XOLAIR looks like and contents of the pack

What XOLAIR looks like:

Solution for injection in pre-filled syringe:

- Clear to slightly opalescent, colorless to pale brownish-yellow solution in a pre-filled syringe.

Solution for injection in pre-filled pen:

- Clear to slightly opalescent, colourless to pale brownish-yellow solution for injection in a pre-filled pen.

Contents of the pack:

XOLAIR pre-filled syringe:

The primary packaging for XOLAIR 75 mg/0.5 mL and 150 mg/1.0 mL consists of the following components:

- a type I glass syringe barrel with staked stainless steel needle where the needle is fixed to the syringe barrel with an adhesive,
- a rubber plunger stopper, and
- a rigid needle shield composed of a rubber needle shield covered by a rigid shell, which are assembled with a needle safety device.

XOLAIR solution for injection in autoinjector:

The primary packaging for XOLAIR 75 mg/0.5 mL and 150 mg/1.0 mL consists of the following components:

- a type I glass syringe barrel with a staked stainless steel needle where the needle is fixed to the syringe barrel with an adhesive,
- a rubber plunger stopper, and
- a rigid needle shield composed of a rubber needle shield covered by a rigid shell, which are enclosed in an autoinjector.

Holder of Certificate of Registration and Manufacturer

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This leaflet was last revised in

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Registration number

XOLAIR 75 mg/0,5 ml, Solution for injection in pre-filled syringe: 55/34/0713

XOLAIR 150 mg/1,0 ml, Solution for injection in pre-filled syringe: 55/34/0714

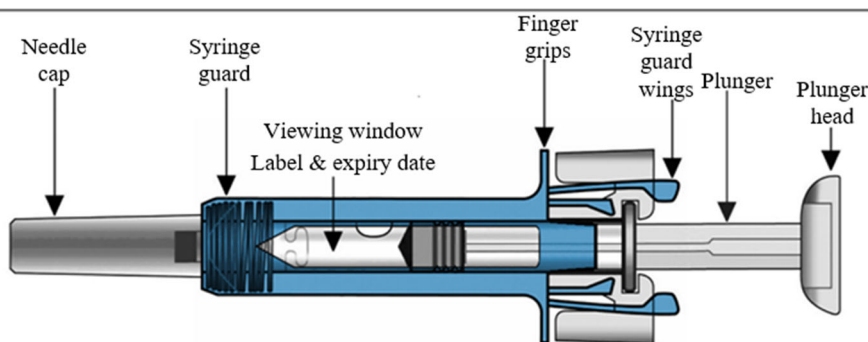
Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

INSTRUCTIONS FOR USE OF XOLAIR PRE-FILLED SYRINGE (pre-filled syringe with 26 gauge staked needle)

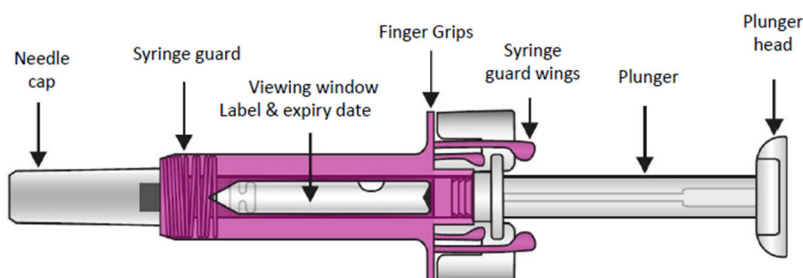
- Read ALL the way through these instructions before injecting.
- If your doctor decides that you or a caregiver may be able to give your injections of XOLAIR at home, you need to be trained by your doctor, nurse or pharmacist before you inject yourself or others.
- Children (6 to less than 12 years 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 75 mg pre-filled syringe



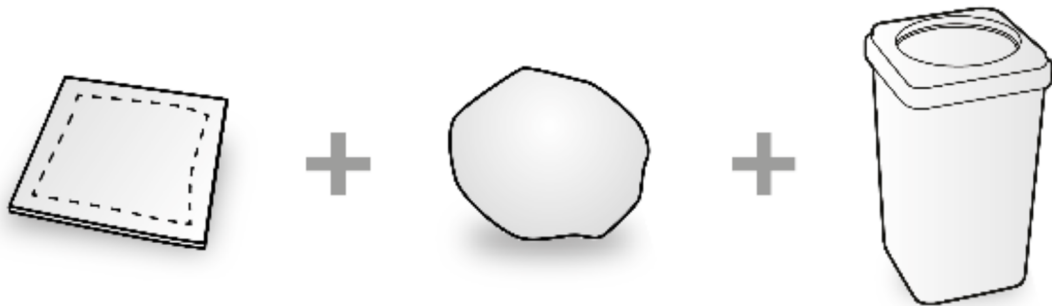
- After the medicine has been injected the syringe guard will be activated to cover the needle.
- This is intended to protect against accidental needle stick injuries.

Your Xolair 150 mg 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 needlestick 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.

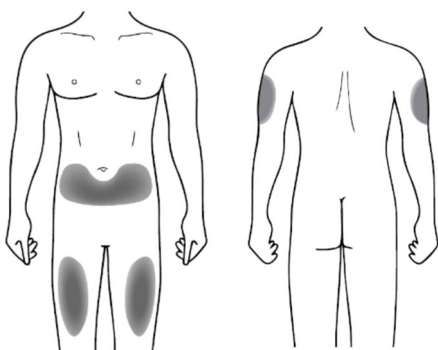
Storage of the Xolair pre-filled syringe

- 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 (it will take 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.



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.

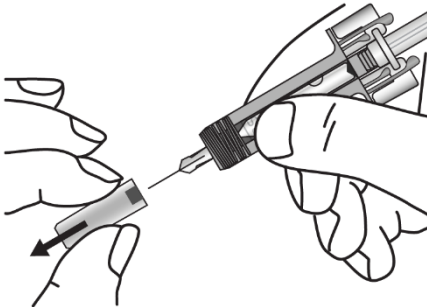
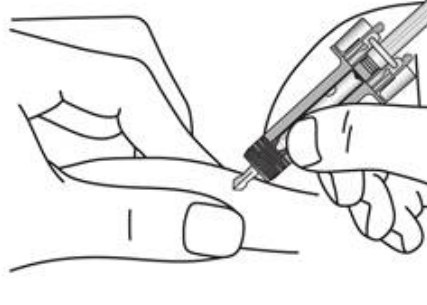
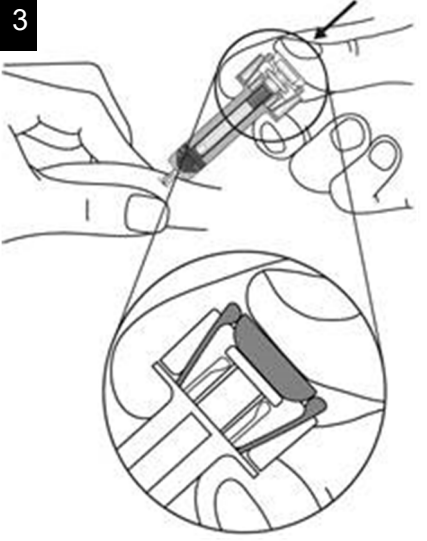
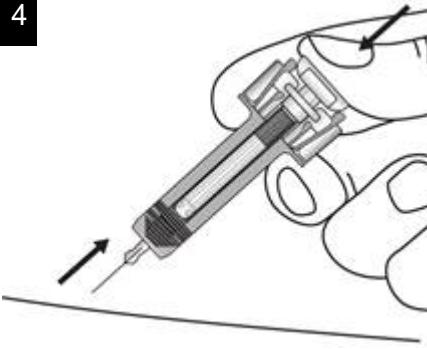
The following table gives examples of how many injections of each dose strength you need for a given dose:

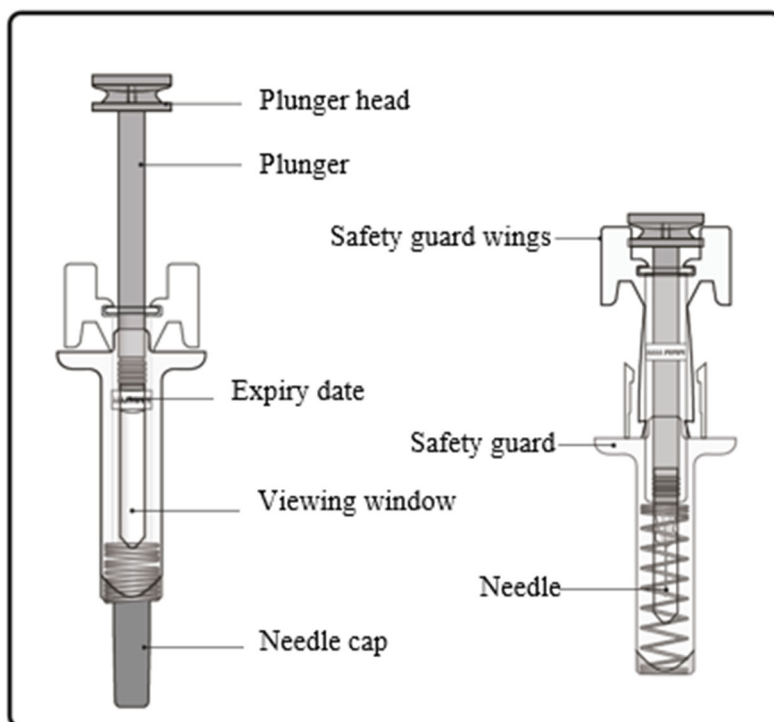
Dose	Syringes needed for the dose	
75 mg	1 blue (75 mg)	
150 mg	1 purple (150 mg)	
225 mg	1 blue (75 mg) + 1 purple (150 mg)	 
300 mg	2 purple (150 mg)	
375 mg	1 blue (75 mg) + 2 purple (150 mg)	 
450 mg	3 purple (150 mg)	
525 mg	1 blue (75 mg) + 3 purple (150 mg)	 
600 mg	4 purple (150 mg)	

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 purple syringe guard, lift the syringe out of the tray.
5. Inspect the syringe. The liquid should be clear to slightly cloudy. Its colour may vary from colourless 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

1 	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.
2 	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.
3 	Hold the syringe as shown. Slowly depress the plunger as far as it will go so that the plunger head is completely between the syringe guard wings.
4 	Keep the plunger fully depressed while you carefully lift the needle straight out from the injection site.



Important information you need to know before injecting Xolair

- Xolair is for subcutaneous injection only (inject directly into fatty layer under the skin).
- **Do not** use the pre-filled syringe if either the seal on the outer carton or the seal of the plastic tray is broken.
- **Do not** use if the pre-filled syringe has been dropped onto a hard surface or dropped after removing the needle cap.
- **Do not** inject if the pre-filled syringe has been kept out of the refrigerator for more than a total of 48 hours. Dispose of it (see Step 12) and use a new pre-filled syringe for your injection.
- The pre-filled syringe has a safety guard that will be activated to cover the needle after the injection is finished. The safety guard will help to prevent needlestick injuries to anyone who handles the pre-filled syringe after injection.
- **Do not** try to re-use or take apart the pre-filled syringe.
- **Do not** pull back on the plunger.

Store Xolair

- Store in a refrigerator (2°C to 8°C). The carton containing the pre-filled syringe can be stored for a total time of 48 hours at room temperature (25°C) before use. It can be placed back in the refrigerator if necessary.
- **Do not** freeze.
- Keep the pre-filled syringe in the original carton until ready to use in order to protect from light.
- Keep the pre-filled syringe out of sight and reach of children.

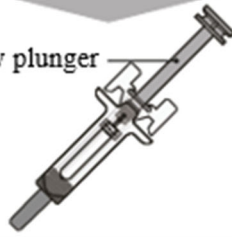
Dosing table

Xolair pre-filled syringes are available in 3 dose strengths (one pre-filled syringe in each carton). These instructions are to be used for all 3 dose strengths.

Depending on the dose prescribed to you by your doctor, you may need to select one or more pre-filled syringes, and inject the contents of them all in order to deliver your full dose. The Dosing Table below shows the combination of pre-filled syringes needed to deliver your full dose.

	Important: If the dose is for a child under age 12 it is recommended to use only blue (75 mg) and purple (150 mg) pre-filled syringes. Refer to the Dosing Table below for the recommended combination of pre-filled syringes for children under age 12.
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Contact your doctor if you have questions on the Dosing Table.

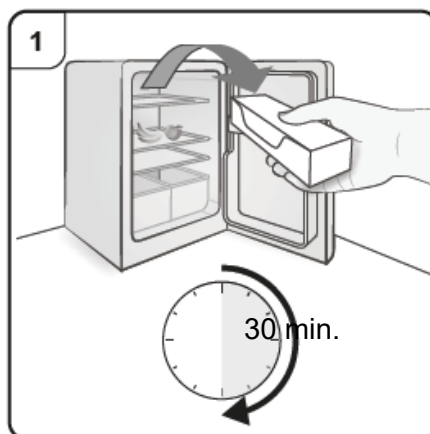
Xolair 75 mg pre-filled syringe with a blue plunger		Xolair 150 mg pre-filled syringe with a purple plunger		Xolair 300 mg pre-filled syringe with a gray plunger	
Blue plunger 		Purple plunger 		Gray plunger 	
DOSE	Prefilled syringes needed for dose	Blue 75 mg	Purple 150 mg	Gray 300 mg	
75 mg	1 blue				
150 mg	1 purple				
225 mg	1 blue + 1 purple				
300 mg (ages 12 and up)	1 gray				
300 mg (children under age 12)	2 purple		 		
375 mg (ages 12 and up)	1 blue + 1 gray				
375 mg (children under age 12)	1 blue + 2 purple		 		
450 mg (ages 12 and up)	1 purple + 1 gray				
450 mg (children under age 12)	3 purple		  		
525 mg (ages 12 and up)	1 blue + 1 purple + 1 gray				
525 mg (children under age 12)	1 blue + 3 purple		  		
600 mg (ages 12 and up)	2 gray			 	
600 mg (children under age 12)	4 purple		   		

Prepare to inject Xolair

Step 1. Bring to room temperature

Take the carton containing the pre-filled syringe out of the refrigerator and **leave it unopened so that it reaches room temperature (minimum 30 minutes)**.

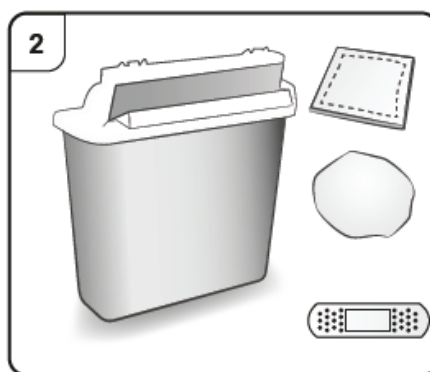
Note: If you need more than one pre-filled syringe (one pre-filled syringe per carton) to deliver your full dose (See Dosing Table), take all the cartons out of the refrigerator at the same time.



Step 2. Gather supplies

You will need the following supplies (not included in the carton):

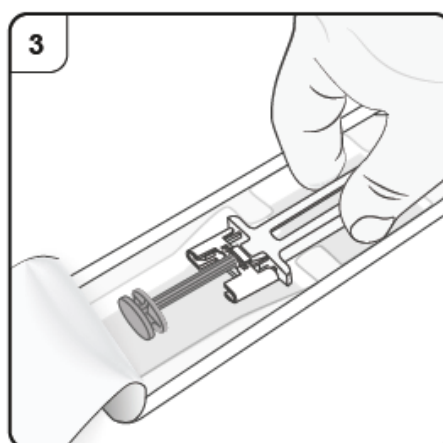
- Alcohol wipe
- Cotton ball or gauze pad
- Sharps disposal container
- Adhesive plaster



Step 3. Unpack

Open the plastic tray by peeling away the cover. Remove the pre-filled syringe by holding it in the middle as shown.

Do not remove the needle cap until you are ready to inject.



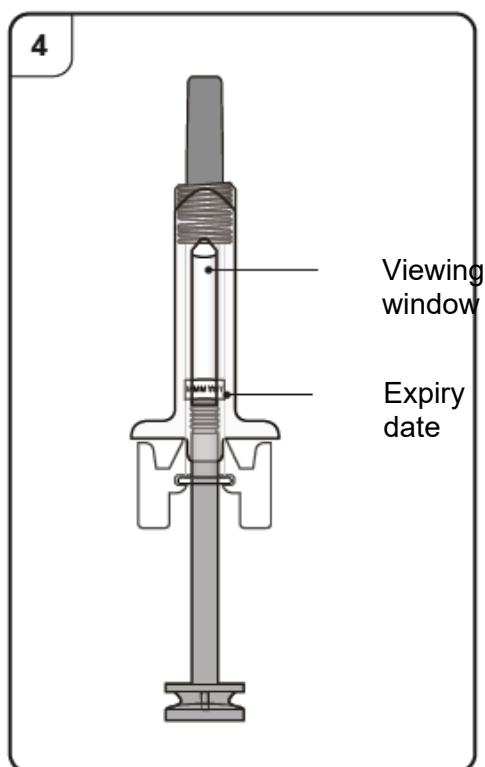
Step 4. Inspect the pre-filled syringe

Look through the viewing window of the pre-filled syringe.

The liquid inside should be clear to slightly cloudy. Its color may vary from colorless to pale brownish-yellow. You may see air bubbles in the liquid, which is normal. Do not try to remove the air.

- Do not use the pre-filled syringe if the liquid contains particles, or if the liquid looks distinctly cloudy or distinctly brown.
- Do not use the pre-filled syringe if it looks damaged or if it has leaked.
- Do not use the pre-filled syringe after the expiry date (EXP), which is printed on the pre-filled syringe label and carton.

In all of these cases, contact your doctor, nurse or pharmacist.



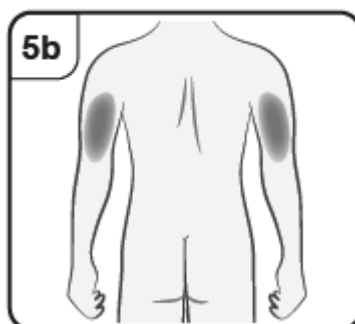
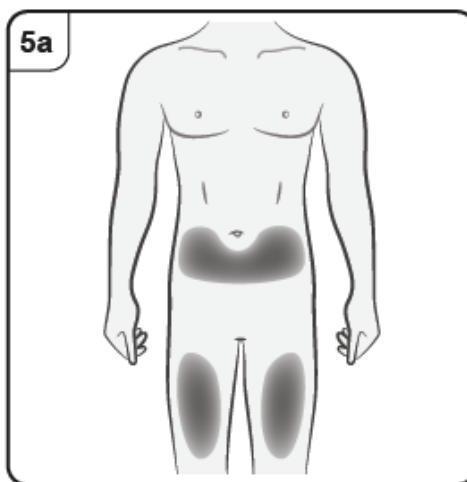
Step 5. Choose injection site

You should inject into the front of the thighs or the lower stomach area but not the area 5 cm around the belly button.

Do not inject into skin that is tender, bruised, red, scaly, hard or into areas with scars or stretch marks.

Note: If you need more than one pre-filled syringe to deliver your full dose, make sure your injections are at least 2 cm apart.

If your caregiver, doctor or nurse is giving you the injection, they may also inject into the outer upper arm.



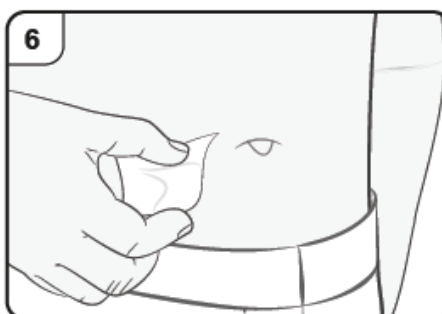
Inject with Xolair

Step 6. Clean injection site

Clean your hands.

Clean the chosen injection site with an alcohol wipe. Leave it to dry before injecting.

Do not touch or blow on the cleaned skin before injecting.

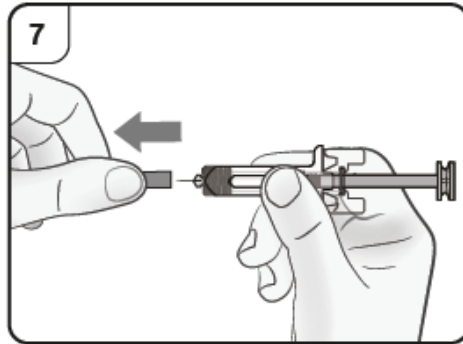


Step 7. Remove needle cap

Firmly pull straight to remove the needle cap from the pre-filled syringe. You may see a drop of liquid at the end of the needle. This is normal.

Do not put the needle cap back on.

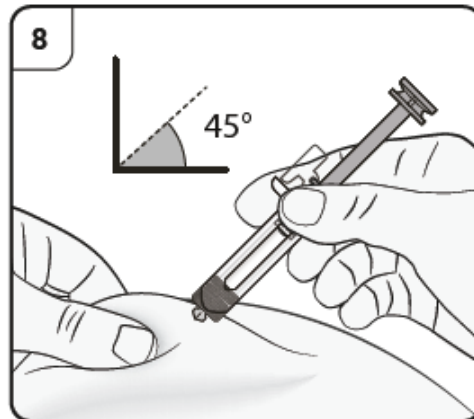
Throw away the needle cap.



Step 8. Insert needle

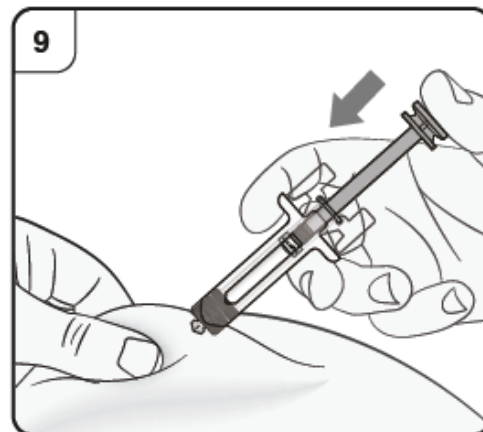
Gently pinch the skin at the injection site and hold the pinch throughout the injection. With the other hand insert the needle into the skin at an angle of approximately 45 degrees as shown.

Do not press the plunger while inserting the needle.



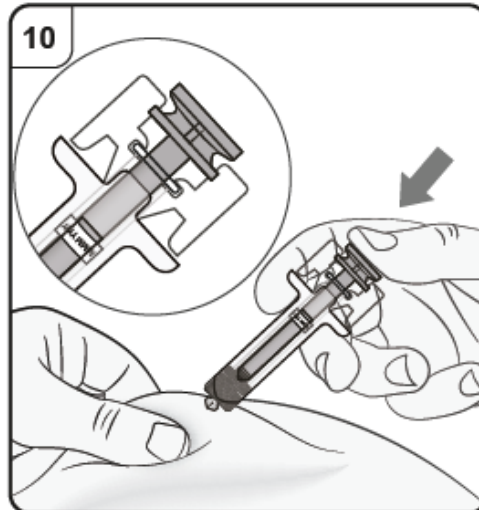
Step 9. Start injection

Continue to pinch the skin. Slowly press the plunger **as far as it will go**. This will ensure that a full dose is injected.



Step 10. Complete injection

Confirm that the plunger head is between the safety guard wings as shown. This will ensure that the safety guard has been activated and will cover the needle after the injection is finished.



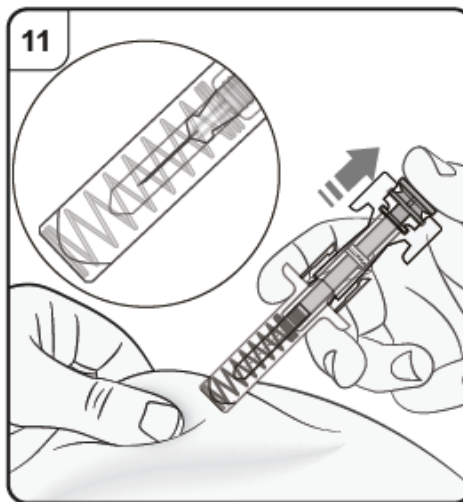
Step 11. Release plunger

Keeping the pre-filled syringe at the injection site, slowly release the plunger until the needle is covered by the safety guard. Remove the pre-filled syringe from the injection site and release the pinch.

There may be a small amount of blood at the injection site. You can press a cotton ball or gauze pad over the injection site until any bleeding stops. **Do not** rub the injection site. If needed, cover the injection site with a small adhesive plaster.

Note: If you need more than one pre-filled syringe to deliver your full dose, throw away the used pre-filled syringe as described in Step 12.

Repeat Step 2 to Step 12 again for all the pre-filled syringes needed to deliver your full dose.



Carry out the injections immediately one after another.

Make sure the injections are at least 2 cm apart.

After the injection

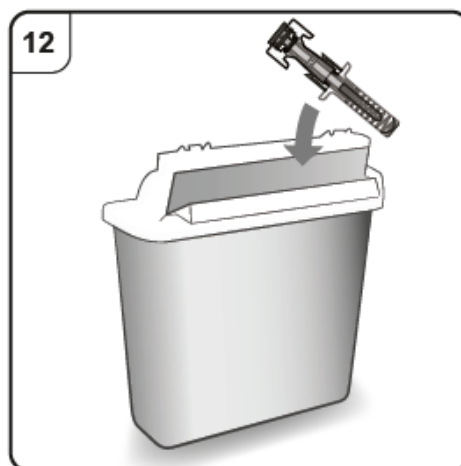
Step 12. Dispose of the pre-filled syringe

Put the used pre-filled syringe in a sharps disposal container (i.e. a puncture-resistant closable container, or similar) immediately after use.

Do not throw away the pre-filled syringe into household waste.

Do not try to put the needle cap back onto the syringe.

Talk to your doctor or pharmacist about proper disposal of the sharps disposal container. There may be local regulations for disposal.



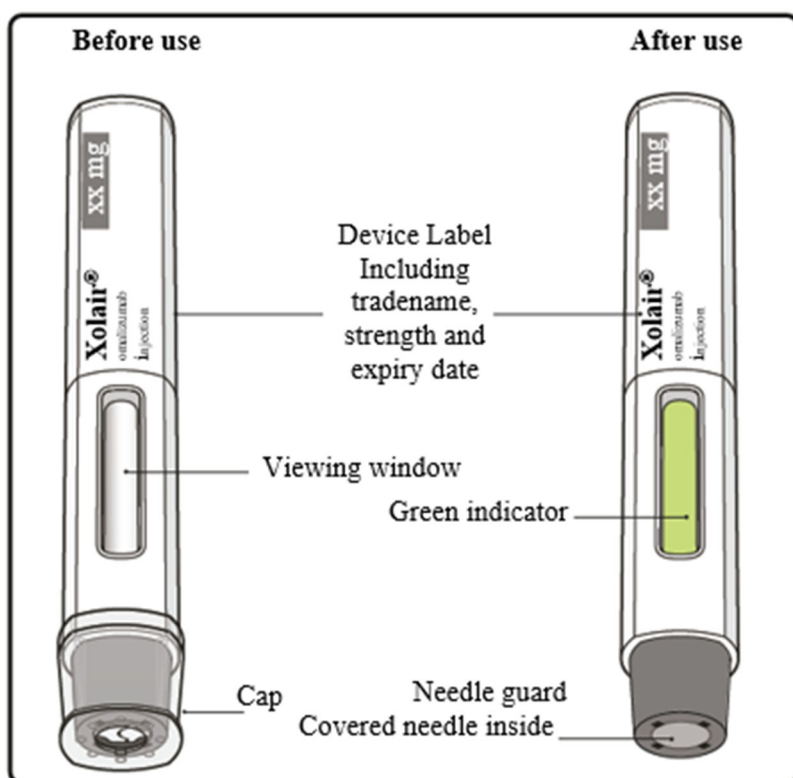
Instructions for use and handling - Xolair solution for injection in pre-filled pen

This “Instructions for Use” contains information on how to inject Xolair.

If your doctor decides that you or your caregiver may be able to give your injections of Xolair at home, ensure that your doctor or nurse shows you or your caregiver how to prepare and inject with the Xolair pen before you use it for the first time.

This Xolair pen is intended to be used for patients ages 12 and up.

Be sure that you read and understand this “Instructions for Use” before injecting with the Xolair pen. Talk to your doctor if you have any questions.



Important information you need to know before injecting Xolair

- Xolair is for subcutaneous injection only (inject directly into fatty layer under the skin).
- **Do not** use the pen if the seal on the outer carton is broken.
- **Do not** use if the pen has been dropped after removing the cap.
- **Do not** inject if the pen has been kept out of the refrigerator for more than a total of 48 hours. Dispose of it (see Step 13) and use a new pen for your injection.
- **Do not** touch or push the needle guard as you could get injured. Touching or pushing on the needle guard could cause a needlestick injury.
- **Do not** try to re-use or take apart the pen.
- **Do not** try to reattach the cap once it has been taken off.

Store Xolair

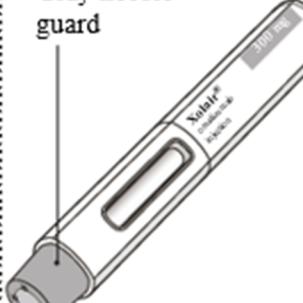
- Store in a refrigerator (2 °C and 8 °C). The carton containing the pen can be stored for a total time of 48 hours at room temperature (25 °C) before use. It can be placed back in the refrigerator if necessary.
- **Do not** freeze.
- Keep the pen in the original carton until ready to use in order to protect from light.
- Keep the pen out of sight and reach of children.

Dosing table

Xolair pens are available in 3 dose strengths (one pen in each carton). These instructions are to be used for all 3 dose strengths.

Depending on the dose prescribed to you by your doctor, you may need to select one or more pens, and inject the contents of them all in order to deliver your full dose. The Dosing Table below shows the combination of pens needed to deliver your full dose.

Contact your doctor if you have questions on the Dosing Table.

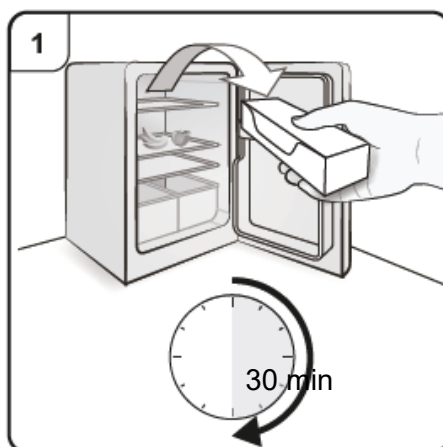
Xolair 75 mg pen with a blue needle guard		Xolair 150 mg pen with a purple needle guard		Xolair 300 mg pen with a gray needle guard	
Blue needle guard		Purple needle guard		Gray needle guard	
					
Dose	Number of pens needed for the dose	Blue 75 mg	Purple 150 mg	Gray 300 mg	
75 mg	1 blue				
150 mg	1 purple				
225 mg	1 blue + 1 purple				
300 mg	1 gray				
375 mg	1 blue + 1 gray				
450 mg	1 purple + 1 gray				
525 mg	1 blue + 1 purple + 1 gray				
600 mg	1 gray + 1 gray				

Prepare to inject Xolair

Step 1. Bring to room temperature

Take the carton containing the pen out of the refrigerator and leave it unopened so that it reaches room temperature (minimum 30 minutes).

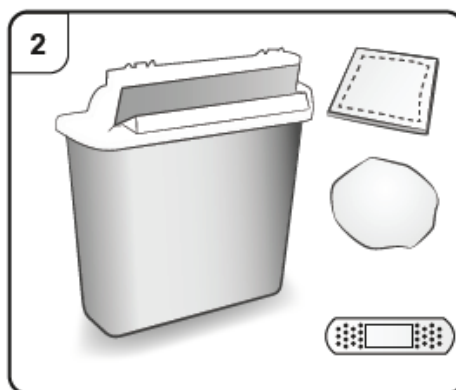
Note: If you need more than one pen (one pen in each carton) to deliver your full dose (see Dosing Table), take all the cartons out of the refrigerator at the same time.



Step 2. Gather supplies

You will need the following supplies (not included in the carton):

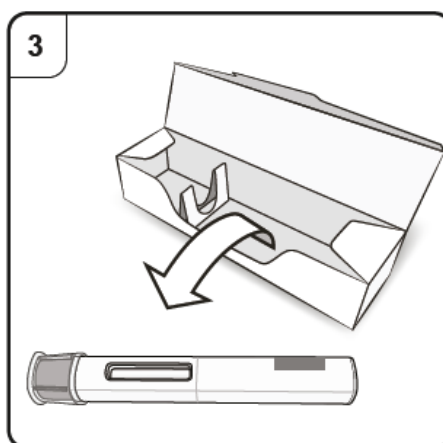
- Alcohol wipe
- Cotton ball or gauze pad
- Sharps disposal container
- Adhesive plaster



Step 3. Unpack

Take the pen out of the outer carton.

Do not remove the cap until you are ready to inject.



Step 4. Inspect the pen

Look through the viewing window of the pen.

The liquid inside should be clear to slightly cloudy. Its color may vary from colorless to pale brownish-yellow. You may see air bubbles in the liquid, which is normal.

- Do not use the pen if the liquid contains particles, or if the liquid looks distinctly cloudy or distinctly brown.
- Do not use the pen if it looks damaged.
- Do not use the pen after the expiry date (EXP), which is printed on the pen label and carton.

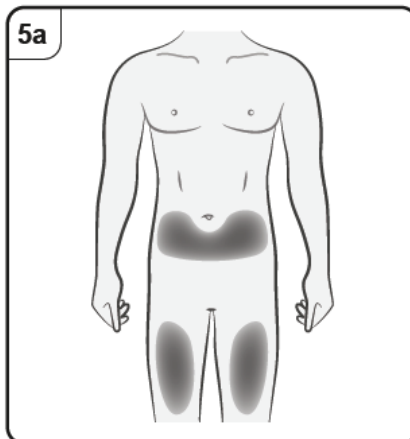
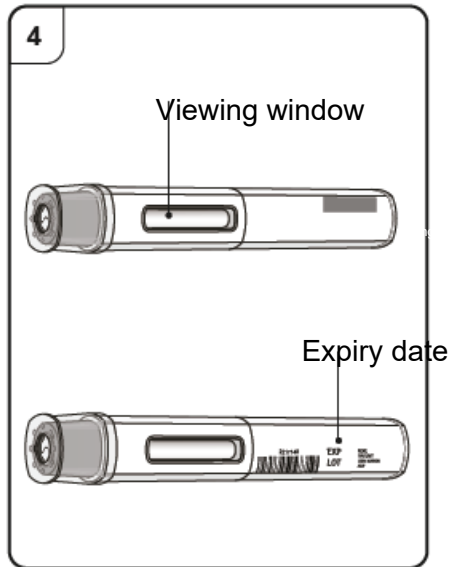
In all of these cases, contact your doctor, nurse or pharmacist.

Step 5. Choose injection site

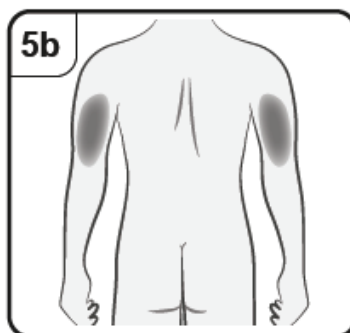
You should inject into the front of the thighs or the lower stomach area but not the area 5 cm around the belly button.

Do not inject into skin that is tender, bruised, red, scaly, and hard or into areas with scars or stretch marks.

Note: If you need more than one pen to deliver your full dose, make sure your injections are at least 2 cm apart.



If a caregiver, doctor or nurse is giving the injection, they may also inject into the outer upper arm.



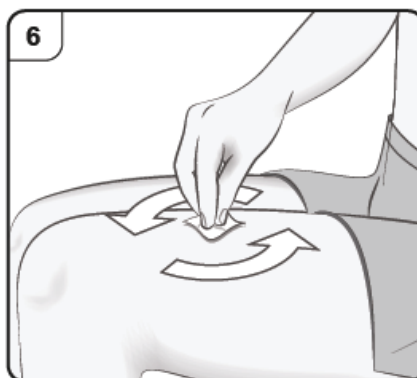
Inject with Xolair

Step 6. Clean injection site

Clean your hands.

Clean the chosen injection site with an alcohol wipe. Leave it to dry before injecting.

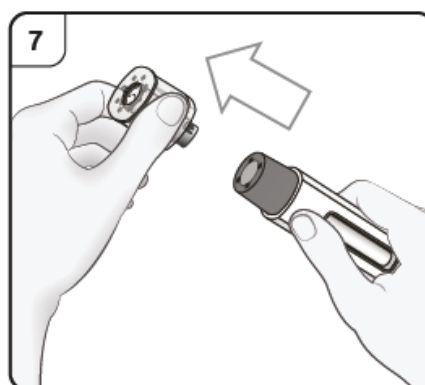
Do not touch or blow on the cleaned skin before injecting.



Step 7. Remove cap

Pull the cap straight off in the direction of the arrow.

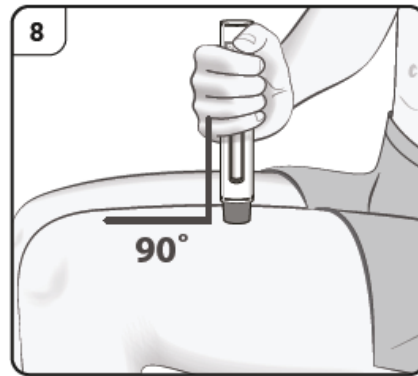
Do not put the cap back on. Throw away the cap.



Step 8. Position the pen

Hold the pen comfortably with the needle guard directly against the skin.

The pen should be at a 90° angle to the skin as shown.

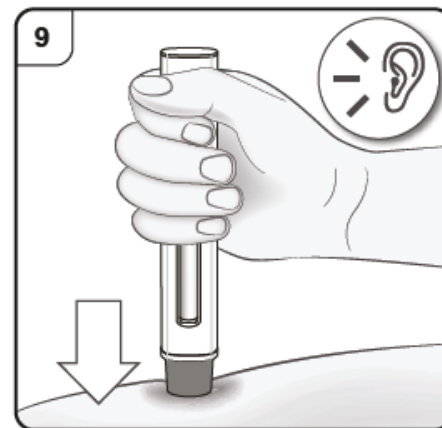


Step 9. Start injection

Push and hold the pen firmly against the skin. Listen for the 1st click which indicates that the injection has started.

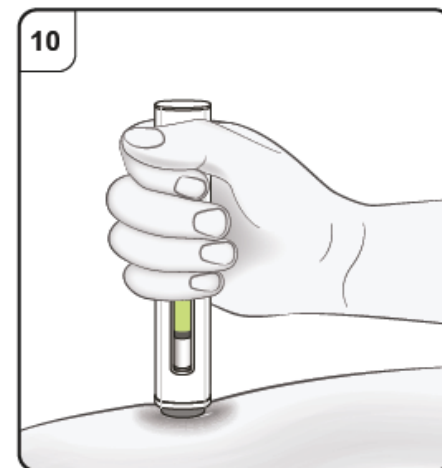


Listen for 'click' sound.



Step 10. Monitor injection

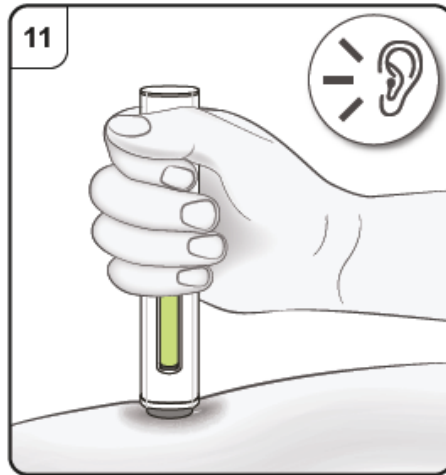
Keep holding the pen firmly down against the skin. The green indicator shows the progress of the injection.



Step 11. Complete injection

Listen for the 2nd click. This indicates the injection is almost complete.

Keep holding the pen in position until the green indicator has stopped moving to make sure the injection is complete. Remove the pen from the skin. The needle is automatically covered by the needle guard. The injection is now complete.



Listen for 'click' sound.

After the injection

Step 12. Check green indicator

If the green indicator has not completely filled the viewing window, contact your doctor or nurse.

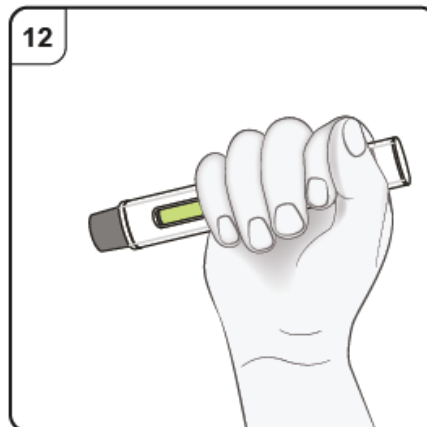
There may be a small amount of blood at the injection site.

You can press a cotton ball or gauze pad over the injection site until any bleeding stops.

Do not rub the injection site. If needed, cover your injection site with a small adhesive plaster.

Note: If you need more than one pen to deliver your full dose, throw away the used pen as described in Step 13.

Repeat Step 2 to Step 13 again for all the pens needed to deliver your full dose.



Carry out the injections immediately one after another.

Make sure the injections are at least 2 cm apart.

Step 13. Dispose of the pen

Put the used pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar) right away after use.

Do not throw away (dispose of) the pen into household waste.

Talk to your doctor or pharmacist about proper disposal of the sharps disposal container. There may be local regulations for disposal.

