

XOLAIR®

Omalizumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xolair.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or healthcare provider.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from

www.medsafe.govt.nz

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Xolair against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Xolair is used for

Allergic asthma

Xolair is used to prevent or relieve the symptoms of allergic asthma in people who are already using preventer puffers containing steroids. Asthma is a disease where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. This may be due to a

reaction to house dust mites, smoke or other irritants.

This medicine can be used in adults and in children aged 6 years or over for the treatment of allergic asthma.

Chronic Rhinosinusitis with Nasal Polyps (Nasal Polyps)

Xolair is used to treat nasal polyps in adults (18 years of age and older) whose severe disease is not well controlled with their current nasal polyps medicines. Xolair helps reduce the size of the polyps and improves symptoms caused by nasal polyps including nasal congestion, loss of sense of smell, post-nasal drip and runny nose.

This medicine can be used in adults aged 18 years and over in nasal polyps. Its use in children and adolescents below 18 years of age with nasal polyps has not been studied.

How Xolair works

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

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 antihistamines.

Xolair works by blocking a substance called immunoglobulin E (also known 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.

Elderly patients are given the same dosage as younger adults.

Ask your doctor if you have any questions about why Xolair has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

Xolair is only available with a doctor's prescription. It is not addictive.

Before you have Xolair

When you must not have it

You should not receive Xolair if you have an allergy to:

- omalizumab (the active ingredient in Xolair) or any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- Wheezing or shortness of breath,
- Severe rash, itching or hives on the skin
- Swelling of the face, lips, tongue, larynx (voice box), windpipe which may cause difficulty in swallowing or breathing or other parts of the body
- Fast heartbeat, dizziness and light headedness

Before you are given it

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

Tell your doctor if you have any of the following conditions:

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

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.

Tell your doctor if you are pregnant or intend to become pregnant or wish to breast-feed your baby.

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

If you have not told your doctor about any of these things, tell him/her before you have Xolair.

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

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Xolair has been used together with other common medicines for asthma or nasal polyps, as well as H1 or H2 antihistamines and LTRAs for chronic spontaneous urticaria. It is possible that some medicines and Xolair could interfere with each other. Your doctor or pharmacist can advise you.

How Xolair is given

Follow all directions given to you by your doctor or healthcare professional carefully.

Xolair is given as a subcutaneous injection. This means that it is injected into the fatty tissue just under the skin.

Xolair is given by pre-filled syringe or pre-filled pen designed to be administered by patients or carers or healthcare professionals.

The injections are usually given in the upper arm or thigh.

Injecting Xolair

You and your doctor will decide if you should inject Xolair yourself. The first 3 doses are recommended to be given by or under the supervision of a healthcare professional.

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

How much Xolair to use

Allergic asthma and Chronic rhinosinusitis with nasal polyps

Your doctor will decide how much Xolair you need and how often you will need it. This will depend on your body weight and the amount of IgE measured in your blood before the start of treatment.

The recommended dose of Xolair ranges from 150 to 1200 mg of Xolair every four weeks. Doses of more than 300 mg are given fortnightly. You will need to continue your current asthma and/or nasal polyps medicines when you start Xolair treatment but after at least 12 weeks, if your symptoms are well controlled, your doctor may be able to reduce or stop other asthma and/or nasal polyps medicines that you are taking. Your doctor will discuss this with you.

Chronic Spontaneous urticaria

You will need 1 or 2 injections of 150 mg 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.

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, immediately tell your doctor, nurse or the Poisons and Hazardous Chemicals National Information Centre, Dunedin (telephone 0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department at your nearest hospital.

No cases of overdose with this medicine have been reported.

While you are having Xolair

Things you must do

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

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

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

Tell any other doctor, dentist or pharmacist who treats you that you are having Xolair.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Xolair affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Xolair.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- bruising, redness or pain at the injection site
- mild skin rash

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

Tell your doctor immediately if you notice any of the following signs:

- abnormal bleeding or bruising
- pain, numbness or tingling in the arms and legs, lumps or raised patches in the skin, weakness and fatigue, loss of appetite, and weight loss

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any signs of an allergic reaction to Xolair.

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

Common symptoms of an allergic reaction may include:

- wheezing or shortness of breath, chest tightness and cough
- a raised, itchy, red rash (hives)
- swollen lips, tongue, eyes or face, stomach pain, feeling sick, vomiting or diarrhoea

Sometimes patients experience a severe allergic reaction. Anaphylaxis is one type of severe allergic reaction which can affect multiple parts of the body. Rare cases of anaphylaxis have been reported with Xolair.

Telephone 111 immediately if severe symptoms of allergic reaction (anaphylaxis) occur.

Symptoms of severe allergic reactions (including any of the above symptoms, plus:

- swelling of the throat and mouth
- difficulty breathing
- light headedness
- confusion
- blue skin or lips
- collapsing and losing consciousness

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.

Churg-Strauss syndrome have been observed in patients treated with Xolair. The symptoms may include one or more of the following: pain, numbness or tingling in the arm and legs, lumps or raised patches in the skin, weakness and fatigue, loss of appetite and weight loss.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Xolair

Storage

- Keep the pre-filled syringe or pen in the original container until it is time to use.
- Keep them in the refrigerator. Do not freeze them.
- Do not store Xolair or any other medicine in the bathroom or near a sink.
- Do not leave them in the car or on window sills.
- Do not use Xolair beyond the expiry date on the label.
- Do not use the product if there are signs of deterioration.
- Do not use Xolair if the pack is damaged or shows signs of tampering.

Heat and dampness can destroy some medicines. Xolair will keep well if it is kept cool and dry.

Keep the medicine where children cannot reach it.

Disposal

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

Product description

What it looks like

Each pack of Xolair contains 1 pre-filled syringe or pre-filled pen.
One syringe or pen of 0.5 mL solution contains 75 mg omalizumab.
One syringe or pen of 1 mL solution contains 150 mg omalizumab.
One syringe or pen of 2 mL solution contains 300 mg omalizumab.

** Not all strengths or dosage forms are marketed*

Ingredients

Each pre-filled syringe or pre-filled pen of Xolair contains the active ingredient, omalizumab. It also contains:
Solution for injection in pre-filled syringe:

- L- arginine hydrochloride
- L-histidine
- L-histidine hydrochloride monohydrate
- polysorbate 20
- water for injections

Sponsor

Xolair is supplied in New Zealand by:
NOVARTIS New Zealand Limited
PO Box 99102
Newmarket
Auckland 1149
New Zealand
Telephone 0800 354 335

® = Registered Trademark

This leaflet was prepared in March 2026.

Internal document code
(xol120326cNZ based on Data sheet
xol120326iNZ)

INSTRUCTIONS FOR USE

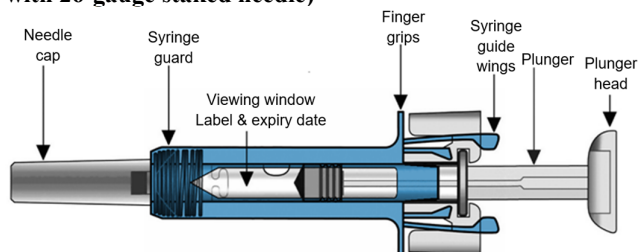
XOLAIR pre-filled syringe (26 gauge staked needle)

omalizumab

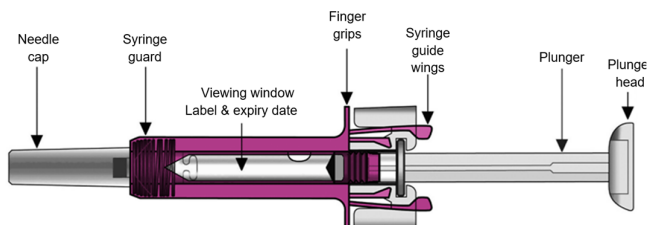
Read ALL the way through these instructions before injecting. If your doctor decides that you or a caregiver may be able to give your injections of Xolair at home, you need to be trained by your doctor, nurse or pharmacist before you inject yourself or others. Children (6 to less than 12 years of age) 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 a Xolair pre-filled syringe 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 (pre-filled syringe with 26-gauge staked needle)



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 needle stick injuries.

Other items you need for your injection:

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



Important safety information

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

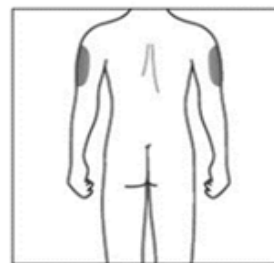
- The needle cap of the syringe may contain dry rubber (latex), which should not be handled by anyone who is sensitive to this substance.

- 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.**
- Prior to use, allow the syringe to reach room temperature (25°C) before preparing it for injection (it will take about 30 minutes). If necessary, the product may be returned to the refrigerator for later use. The total time that the syringe is kept at room temperature must not exceed 48 hours.
- **Do not** try to warm the syringe using an external heat source.
- Do not use the syringe after the expiry date which is stated on the outer box and syringe label. If it has expired, return the entire pack to the pharmacy.

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 centimeters 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.
- If injecting more than once into the same area, ensure a distance of at least 4 cm between injection sites.
- 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.

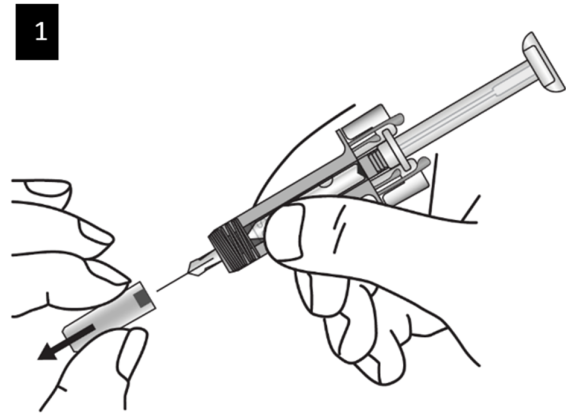
The following table give **EXAMPLES** of how many injections of each strength you need for a given dose.

Please discuss with your doctor how frequent (4 weekly or 2 weekly) you need to administer each dose

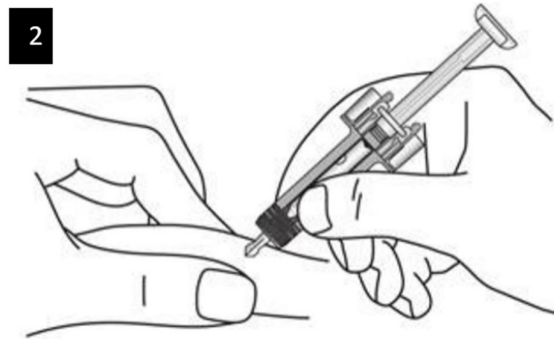
Dose	Syringes needed for the dose	
75 mg	1 blue (75 mg) 	
150 mg	1 purple (150 mg) 	
225 mg	1 blue (75 mg) +	1 purple (150 mg) 
300 mg	2 purple (150 mg) 	
375 mg	1 blue (75 mg) +	2 purple (150 mg) 
450 mg	3 purple (150 mg) 	
525 mg	1 blue (75 mg) +	3 purple (150 mg) 
600 mg	4 purple (150 mg) 	

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 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.)

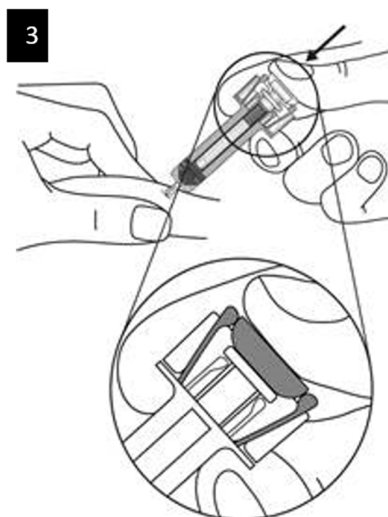
How to use the Xolair pre-filled syringe



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.



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.

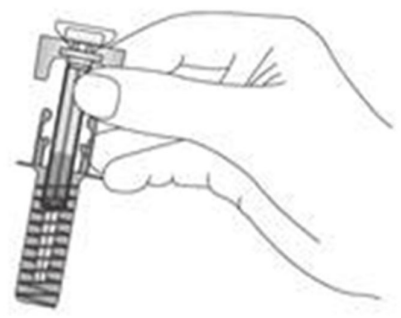


Hold the syringe as shown. **Slowly** depress the plunger **as far as it will go** so that the plunger head is completely between the syringe guard wings.

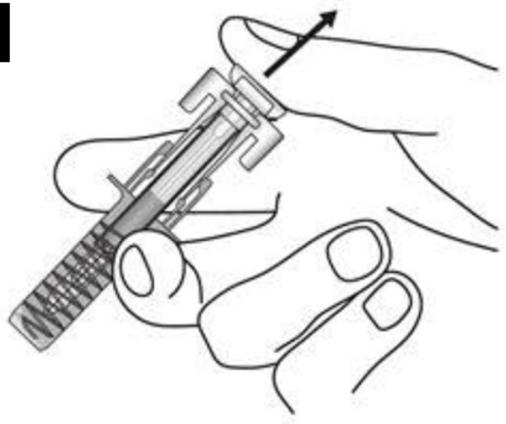
4



Keep the plunger fully depressed while you carefully lift the needle straight out from the injection site.



5



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.

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.

INSTRUCTIONS FOR USE

XOLAIR pre-filled syringe (27 gauge staked needle)

omalizumab

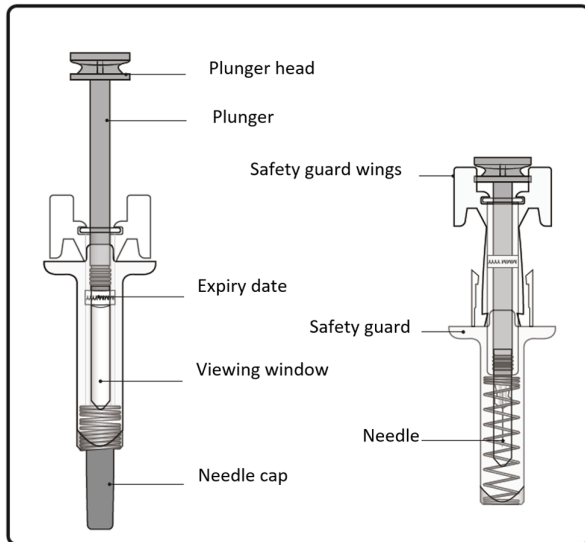
This “Instructions for Use” contains information on how to inject Xolair.

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 pre-filled syringe before you use it for the first time.

Children below 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 injections after proper training.

Be sure that you read and understand this “Instructions for Use” before injecting with the Xolair pre-filled syringe.

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 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.

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

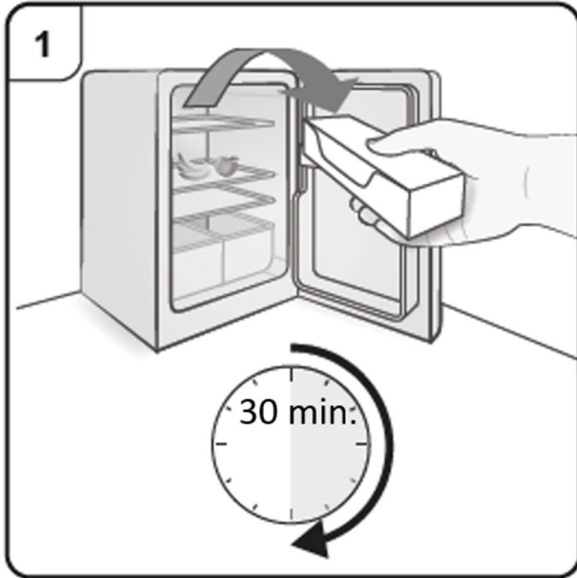
	Xolair 75 mg pre-filled syringe with a blue plunger	Xolair 150 mg pre-filled syringe with a purple plunger	Xolair 300 mg pre-filled syringe with a gray plunger	
	Blue plunger	Purple plunger	Gray plunger	
DOSE	Prefilled syringes needed for dose	Blue 75 mg	Purple 150 mg	Gray 300 mg
75 mg	1 blue			
150 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)**.

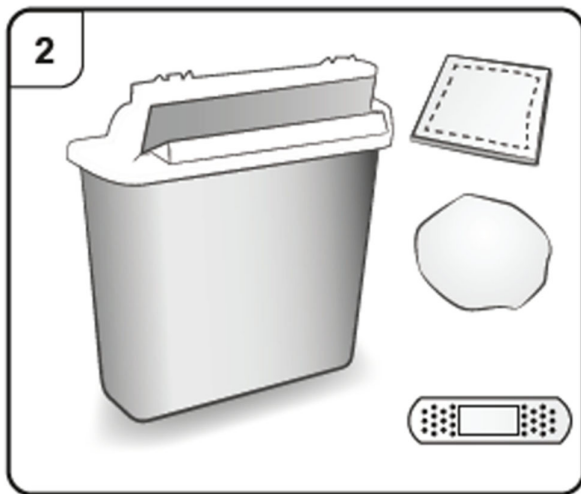
Note: If you need more than one pre-filled syringe (one pre-filled syringe per carton) to deliver your full dose (see Dosing Table), take all the cartons out of the refrigerator at the same time.



Step 2. Gather supplies

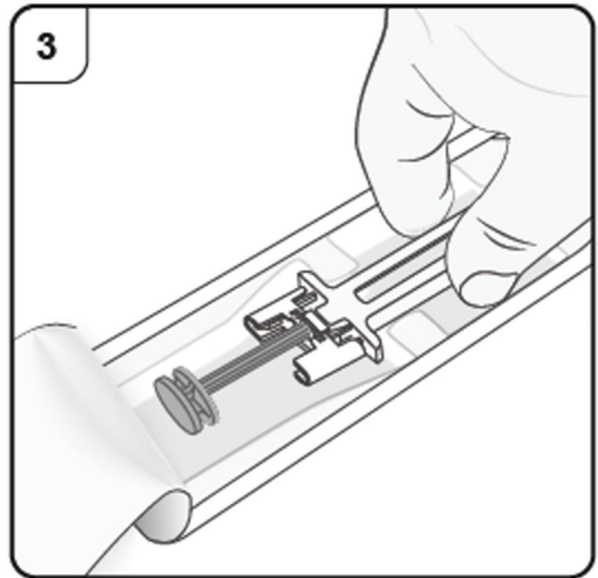
You will need the following supplies (not included in the carton):

- 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.

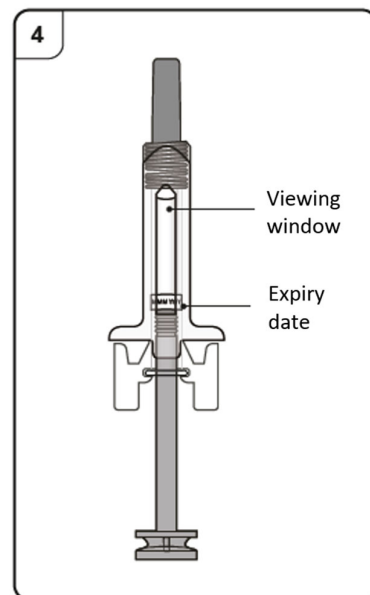


Step 4. Inspect the pre-filled syringe

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.

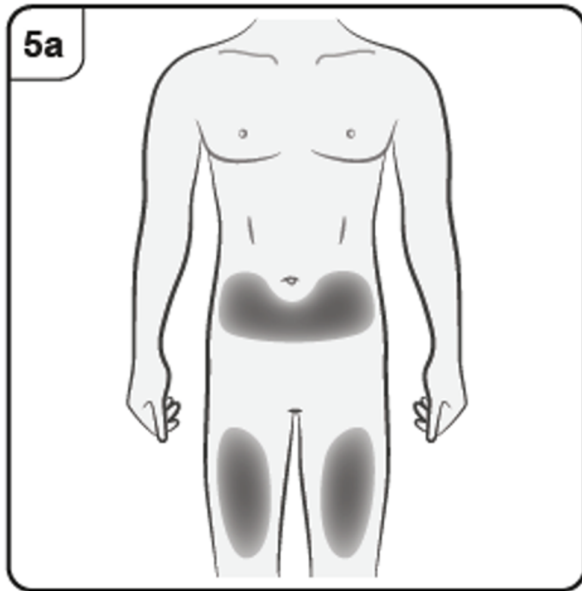
- **Do not** use the pre-filled syringe if the liquid contains particles, or if the liquid looks distinctly cloudy or distinctly brown.
- **Do not** use the pre-filled syringe if it looks damaged or if it has leaked.
- **Do not** use the pre-filled syringe after the expiry date (EXP), which is printed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

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

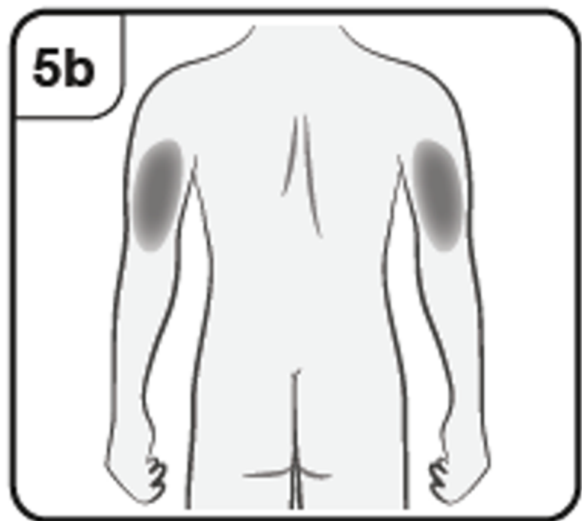


Step 5. Choose injection site

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 or 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.



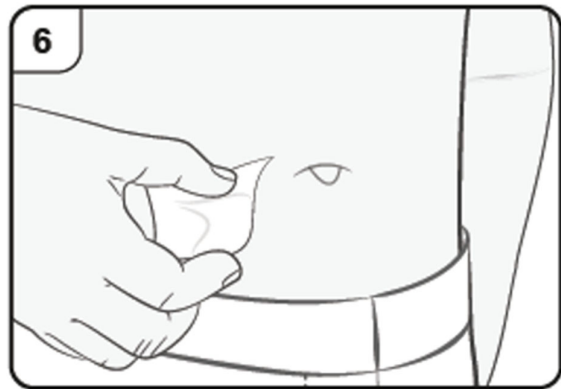
Inject with Xolair

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.

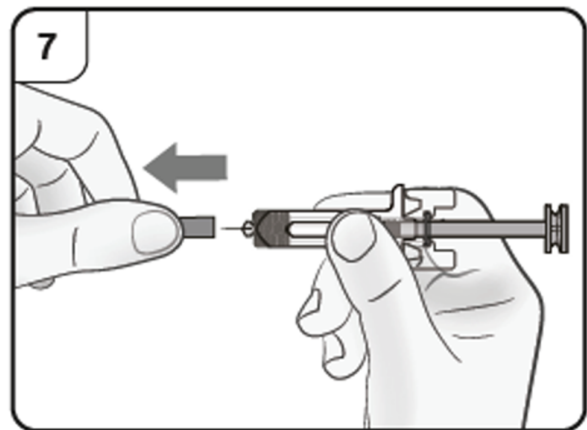


Step 7. Remove needle cap

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.

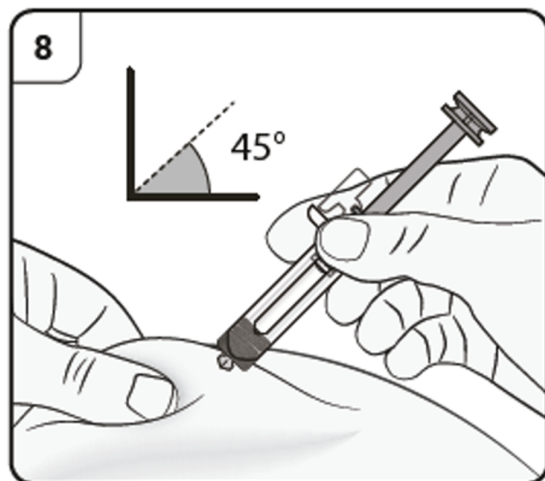
Throw away the needle cap.



Step 8. Insert needle

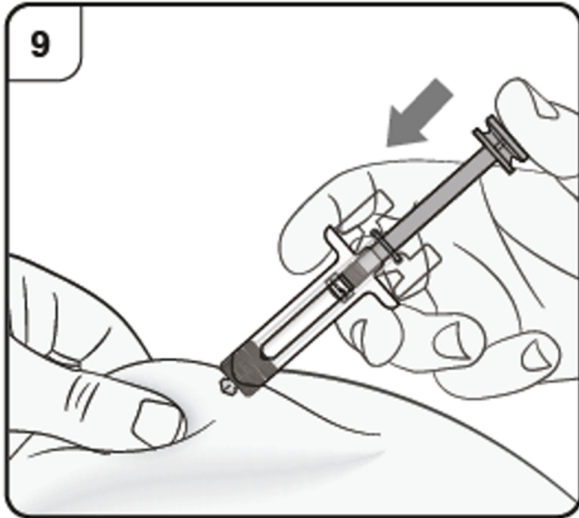
Gently pinch the skin at the injection site and hold the pinch throughout the injection. With the other hand insert the needle into the skin at an angle of approximately 45 degrees as shown.

Do not press the plunger while inserting the needle.



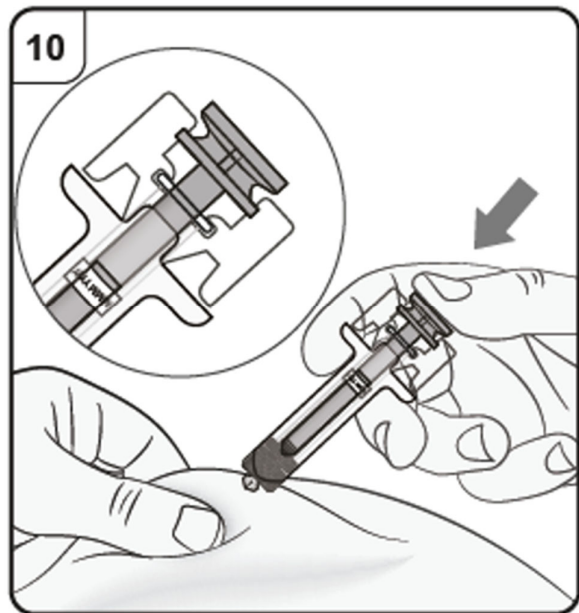
Step 9. Start injection

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

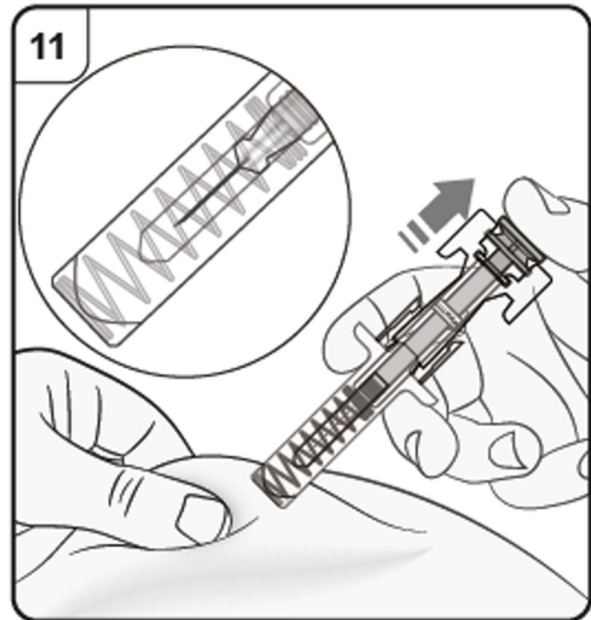
Confirm that the plunger head is between the safety guard wings as shown. This will ensure that the safety guard has been activated and will cover the needle after the injection is finished.



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

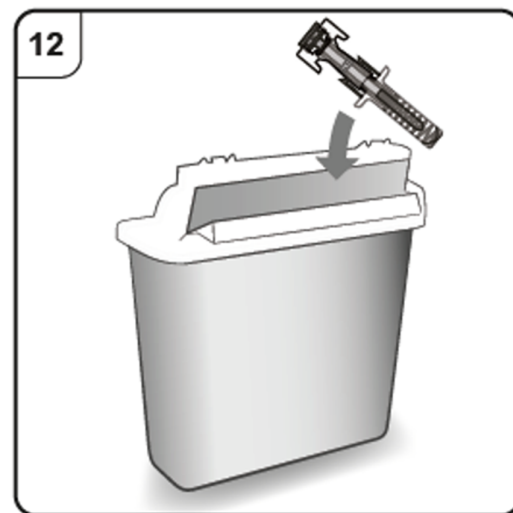
Step 12. Dispose of the pre-filled syringe

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

XOLAIR pre-filled pen

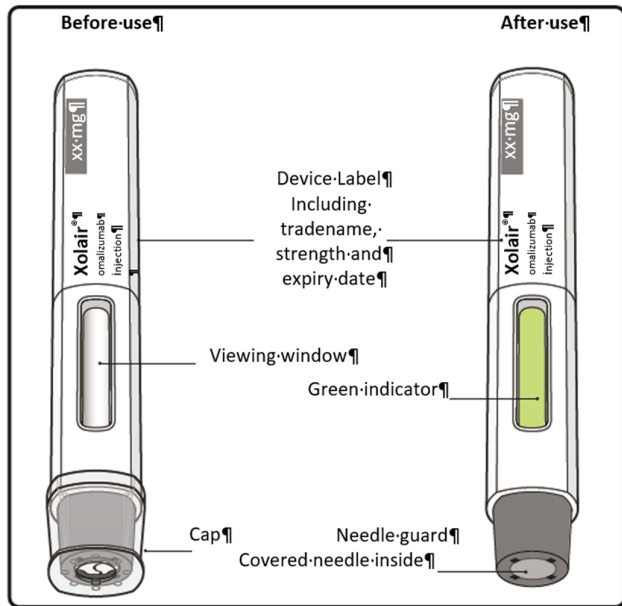
omalizumab

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

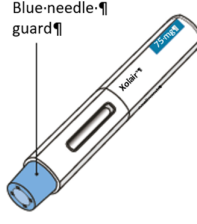
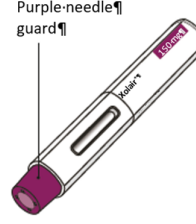
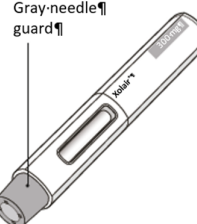













- Store in a refrigerator (2°C and 8°C). The carton containing the pen can be stored for a total time of 48 hours at room temperature (25°C) before use. It can be placed back in the refrigerator if necessary.
- **Do not** freeze.
- Keep the pen in the original carton until ready to use in order to protect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

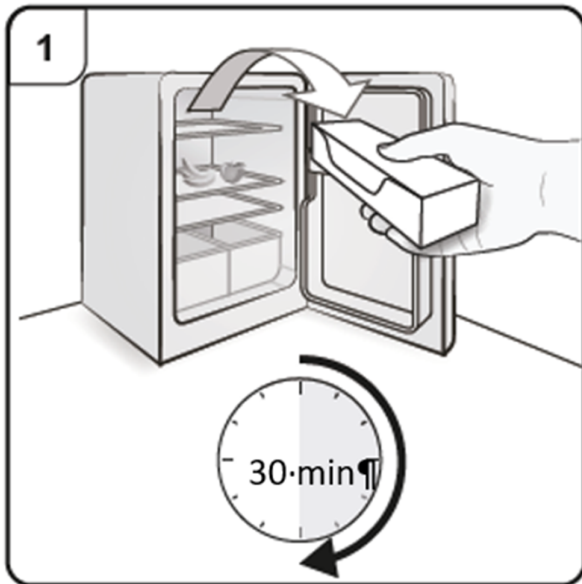
	Xolair-75-mg pen-with-a-blue-needle-guard	Xolair-150-mg pen-with-a-purple-needle-guard	Xolair-300-mg pen-with-a-gray-needle-guard	
				
Dose	Number-of-pens-needed-for-the-dose	Blue 75-mg	Purple 150-mg	Gray 300-mg
75-mg	1-blue			
150-mg	1-purple			
225-mg	1-blue+1-purple			
300-mg	1-gray			
375-mg	1-blue+1-gray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

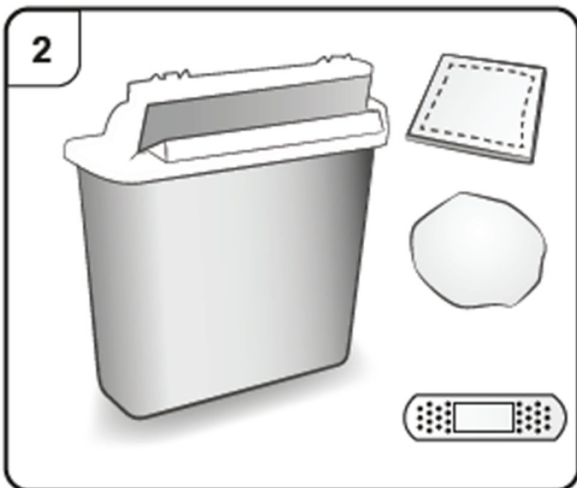
Note: If you need more than one pen (one pen in each carton) to deliver your full dose (see Dosing Table), take all the cartons out of the refrigerator at the same time.



Step 2. Gather supplies

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

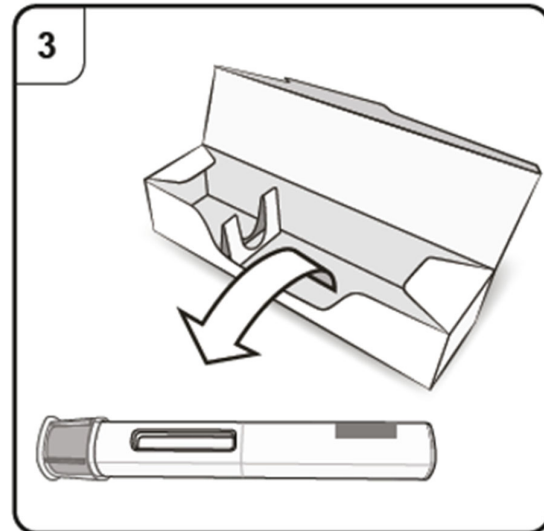
- Alcohol wipe
- Cotton ball or gauze pad
- Sharps disposal container
- Adhesive plaster



Step 3. Unpack

Take the pen out of the outer carton.

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



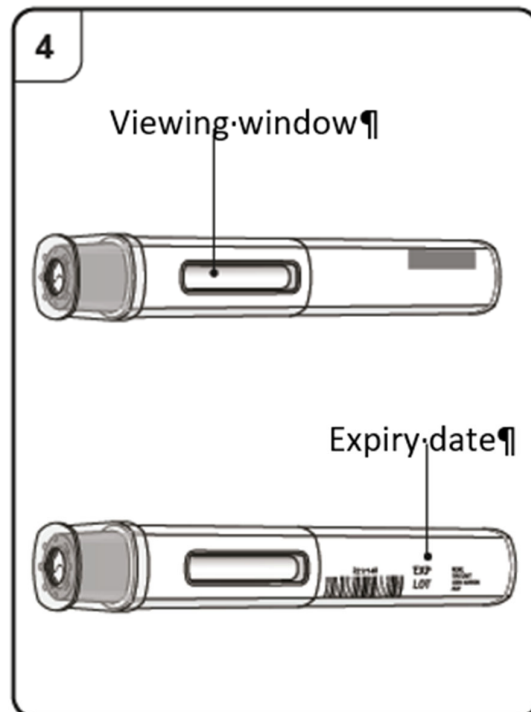
Step 4. Inspect the pen

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.

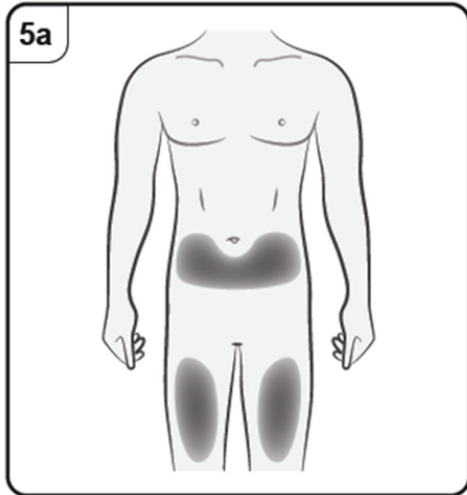
- **Do not** use the pen if the liquid contains particles, or if the liquid looks distinctly cloudy or distinctly brown.
- **Do not** use the pen if it looks damaged.
- **Do not** use the pen after the expiry date (EXP), which is printed on the pen label and carton.

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

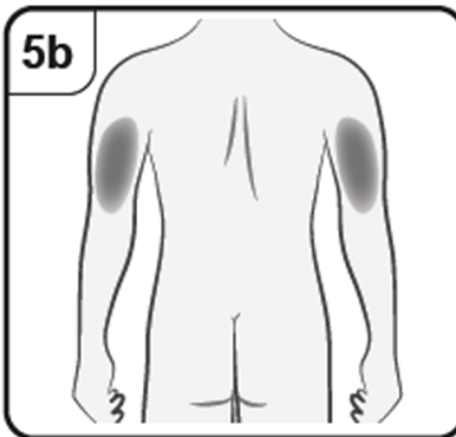


Step 5. Choose injection site

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 or 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.

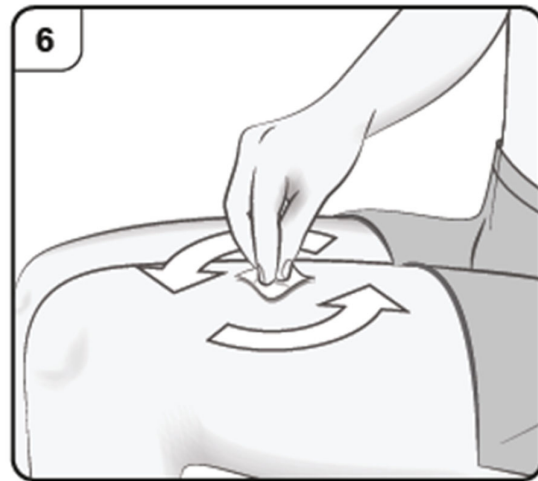


If a caregiver, doctor or nurse is giving the injection, they may also inject into the outer upper arm.

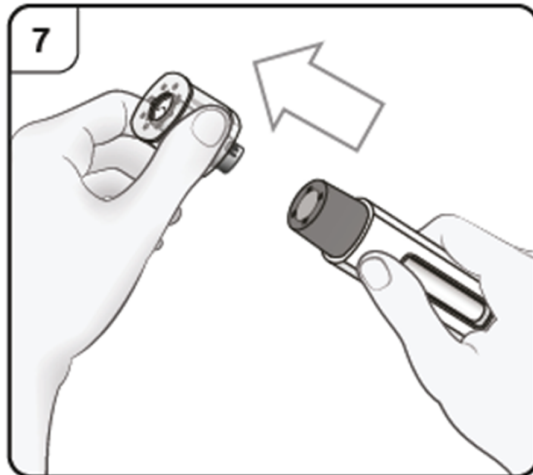


Inject with Xolair
Step 6. Clean injection site

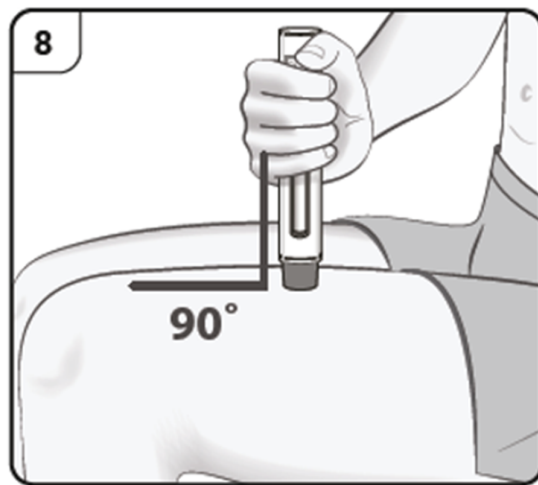
Clean your hands.
Clean the chosen injection site with an alcohol wipe. Leave it to dry before injecting.
Do not touch or blow on the cleaned skin before injecting.



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.

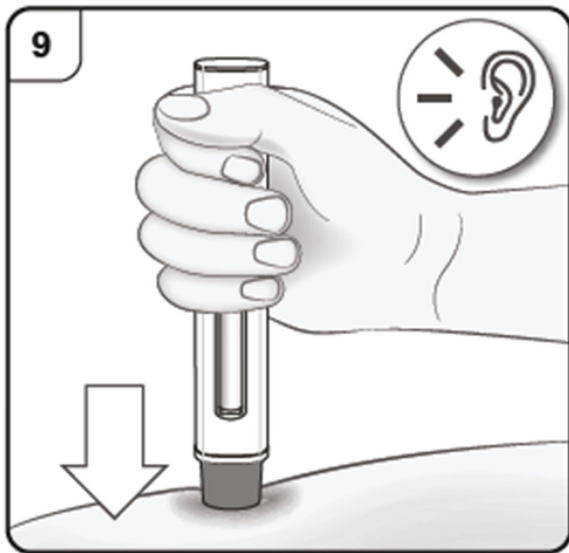


Step 8. Position the pen
Hold the pen comfortably **with the needle guard directly against the skin.**
The pen should be at a 90° angle to the skin as shown.



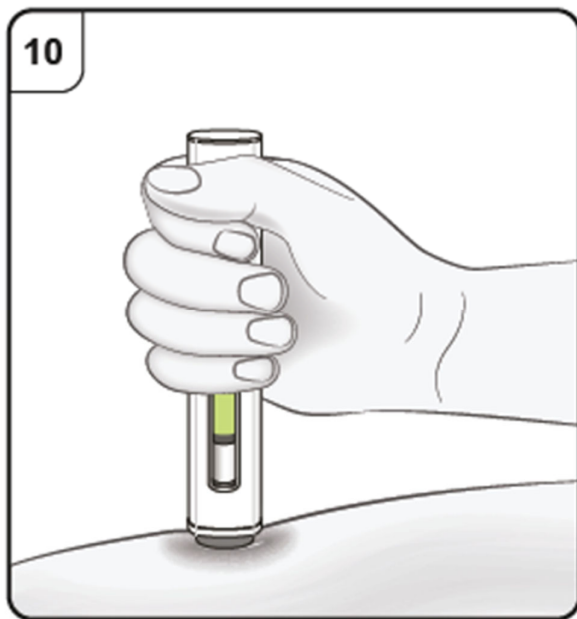
Step 9. Start injection

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.

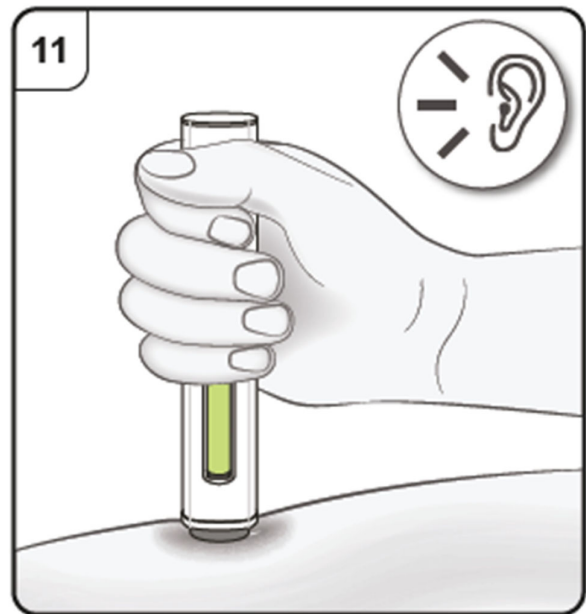


Step 11. Complete injection

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

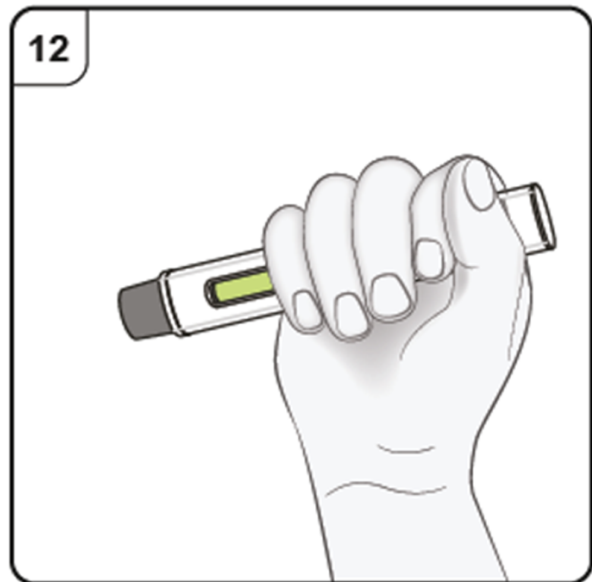
Step 12. Check green indicator

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.

