NOVARTIS

XOLAIR® 150 mg (powder for solution for injection)

XOLAIR® 75 mg and 150 mg (solution for injection)

One vial of XOLAIR 150 mg powder and solvent for solution for injection contains 150 mg of omalizumab

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.

Patient Information Leaflet

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SCHEDULING STATUS S4

XOLAIR 150® mg powder for solution for injection

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

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:

- 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 is a powder for solution for injection.

XOLAIR 150 mg comes as a white to off-white cake (powder) in a small glass vial together with an ampoule containing 2 mL of water for injections. The powder is dissolved in the water before it is injected. Each vial delivers 150 mg of omalizumab.

XOLAIR solution for injection in pre-filled syringe:

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 healthcare provider before being given the injection if:

- 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 years of age. Its use in children below 12 years of age has not been studied sufficiently.

Other medicines and XOLAIR

Always tell your healthcare 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 and breastfeeding and fertility

Pregnancy

- If you are pregnant or breastfeeding your baby while using this medicine, please consult your doctor, pharmacist or other healthcare professional 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 section 4 Possible side effects)*. If this happens to you do not drive or use machines.

XOLAIR contains sucrose

If you are diabetic or have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking XOLAIR. XOLAIR contains sucrose.

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" 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.
- However, in the event of overdosage your doctor will manage the overdosage.

Injecting XOLAIR pre-filled syringe:

- 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.

Injecting XOLAIR pre-filled syringe:

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 healthcare professional 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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of XOLAIR.

How to store XOLAIR

Storage of XOLAIR vial

- Keep out of the reach and sight of children.

- Store in the original package.
- XOLAIR is to be stored at 2 °C to 8 °C in a refrigerated condition.
- Do not freeze.
- XOLAIR can be shipped at ambient temperature (≤ 30 °C) or at 2 °C to 8 °C.
- Do not use after the expiry date.
- Do not store in a bathroom
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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 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.

5. Contents of the pack and other information

What XOLAIR contains:

Powder for solution for injection (vial)

The active substance of XOLAIR is: omalizumab.

The other ingredients of XOLAIR are: sucrose, histidine, histidine hydrochloride monohydrate and polysorbate 20.

An ampoule containing 2 mL of water for injections, which is used to dissolve the powder before injection, is also provided in the pack.

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.

What XOLAIR looks like and contents of the pack

What XOLAIR looks like:

Powder for solution for injection (vial):

- Glass vial containing a white to off-white cake (powder) for solution for injection after reconstitution with 2,0 mL water for injection.
- The reconstituted solution is a colourless to pale brownish-yellow solution.

Solution for injection in pre-filled syringe:

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

Contents of the pack:

XOLAIR powder vial:

- Clear, colourless glass vial with stopper and blue (150 mg) flip-off seal.

Novartis water for injection:

- Clear, colourless glass ampoule containing 2 mL water for injections.

Xolair vials:

- XOLAIR is supplied as packs containing one vial of powder for solution for injection and one ampoule of water for injections.

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 glass syringe barrel with staked needle where the needle is fixed to the syringe barrel with an adhesive,
- a latex free rubber plunger stopper, and
- a rigid needle shield composed of a rubber needle shield covered by a rigid shell.

Holder of Certificate of Registration

NOVARTIS SOUTH AFRICA (PTY) LTD

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg, South Africa

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XOLAIR 150 mg, Powder for solution for injection: A39/34/0311

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

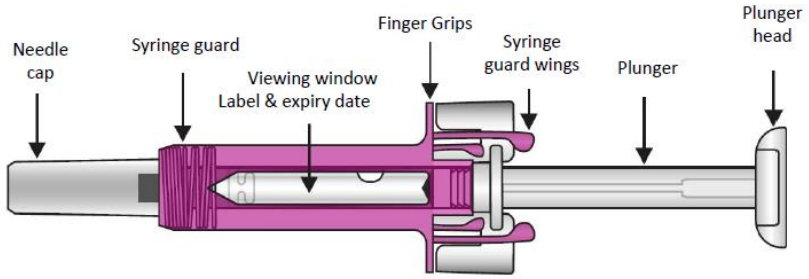
Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

INSTRUCTIONS FOR USE OF XOLAIR PRE-FILLED SYRINGE

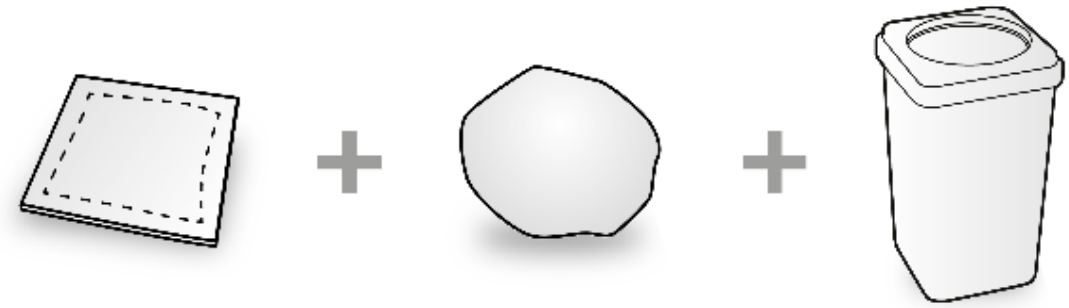
- Read ALL the way through these instructions before injecting.
- If your doctor decides that you or a caregiver may be able to give your injections of XOLAIR at home, you need to be trained by your doctor, nurse or pharmacist before you inject yourself or others.
- Children (6 to less than 12 years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

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.

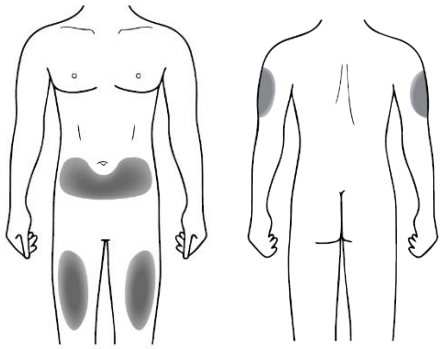
Storage of the XOLAIR pre-filled syringe

- 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.

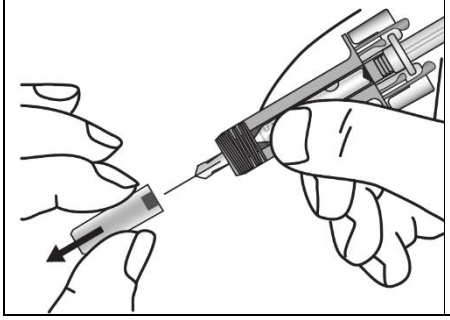
6. Holding the syringe horizontally, look into the viewing window to check the expiry date printed

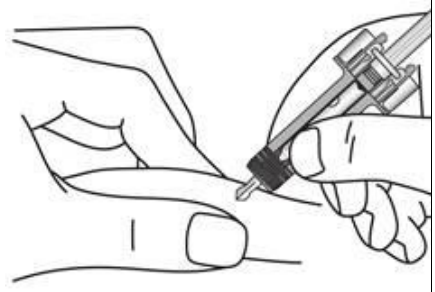
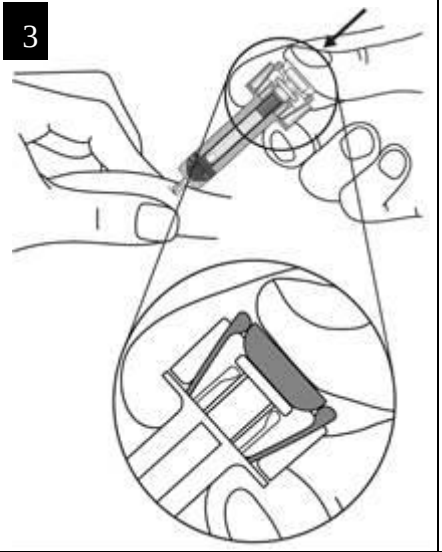
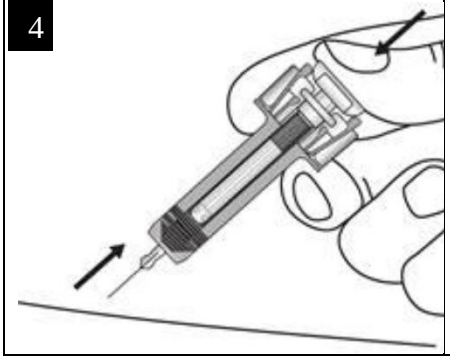
on the label. Note: It is possible to rotate the inner part of the syringe assembly so that the label

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.

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.