

Package leaflet: Information for the user

Xolair® 150 mg solution for injection in pre-filled syringe
(pre-filled syringe with 27-gauge staked needle, purple plunger)
Xolair® 300 mg solution for injection in pre-filled syringe
omalizumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

Xolair contains the active substance omalizumab. 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 used for the treatment of:

- allergic asthma
- chronic rhinosinusitis (inflammation of the nose and sinuses) with nasal polyps
- chronic spontaneous urticaria (CSU)

Allergic asthma

This medicine is used to prevent asthma from getting worse by controlling symptoms of severe allergic asthma in adults, adolescents and children (6 years of age and older) who are already receiving asthma medicine, but whose asthma symptoms are not well controlled by medicines such as high-dose steroid inhalers and beta-agonist inhalers.

Chronic rhinosinusitis with nasal polyps

This medicine is used to treat chronic rhinosinusitis with 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.

Chronic spontaneous urticaria (CSU)

This medicine is used to treat chronic spontaneous urticaria in adults and adolescents (12 years of age and older) who are already receiving antihistamines but whose CSU symptoms are not well controlled by these medicines.

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, chronic rhinosinusitis with nasal polyps and CSU.

2. What you need to know before you use Xolair

Do not use Xolair:

- if you are allergic to omalizumab or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic to any of the ingredients, tell your doctor as you should not use Xolair.

Warnings and precautions

Talk to your doctor before using Xolair:

- if you have kidney or liver problems.
- if you have a disorder where your own immune system attacks parts of your own body (autoimmune disease).
- if you are travelling to region where infections caused by parasites are common - Xolair may weaken your resistance to such infections.
- if you have had a previous severe allergic reaction (anaphylaxis), for example resulting from a medicine, an insect bite or food.

Xolair does not treat acute asthma symptoms, such as a sudden asthma attack. Therefore Xolair should not be used to treat such symptoms.

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, eczema or hay fever because Xolair has not been studied in these conditions.

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

Xolair can potentially cause serious side effects. You must look out for signs of these conditions while you use Xolair. Seek medical help immediately if you notice any signs indicating a severe allergic reaction or other serious side effects. Such signs are listed under “Serious side effects” in section 4.

It is important that you receive training from your doctor in how to recognise early symptoms of severe allergic reactions, and how to manage these reactions if they occur, before you inject Xolair yourself or before a non-healthcare professional gives you a Xolair injection (see section 3, “How to use Xolair”). The majority of severe allergic reactions occur within the first 3 doses of Xolair.

Children and adolescents

Allergic asthma

Xolair is not recommended for children under 6 years of age. Its use in children under 6 years of age has not been studied.

Chronic rhinosinusitis with nasal polyps

Xolair is not recommended for children and adolescents under 18 years of age. Its use in patients under 18 years of age has not been studied.

Chronic spontaneous urticaria (CSU)

Xolair is not recommended for children under 12 years of age. Its use in children under 12 years of age has not been studied.

Other medicines and Xolair

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking:

- medicines to treat an infection caused by a parasite, as Xolair may reduce the effect of your

- medicines,
- inhaled corticosteroids and other medicines for allergic asthma.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Your doctor will discuss with you the benefits and potential risks of using this medicine during pregnancy.

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

Xolair may pass into breast milk. If you are breast-feeding or plan to breast-feed, ask your doctor for advice before using this medicine.

Driving and using machines

It is unlikely that Xolair will affect your ability to drive and use machines.

3. How to use Xolair

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

How Xolair is used

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

Injecting Xolair

- You and your doctor will decide if you should inject Xolair yourself. The first 3 doses are always given by or under the supervision of a healthcare professional (see section 2).
- It is important to be properly trained on how to inject the medicine before injecting yourself.
- A caregiver (for example a parent) may also give you your Xolair injection after he or she has received proper training.

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

Training to recognise serious allergic reactions

It is also important that you do not inject Xolair yourself until you have been trained by your doctor or nurse on:

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

For more information about the early signs and symptoms of serious allergic reactions, see section 4.

How much 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 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 asthma and/or nasal polyps medicine during Xolair treatment. Do not stop taking any asthma and/or 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. In asthma patients it usually

takes between 12 and 16 weeks to have the full effect.

Chronic spontaneous urticaria (CSU)

You will need two 150 mg injections at a time or one 300 mg injection every four weeks.

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

Use in children and adolescents

Allergic asthma

Xolair can be used in children and adolescents aged 6 years and older, who are already receiving asthma medicine, but whose asthma symptoms are not well controlled by medicines such as high dose steroid inhalers and beta-agonist inhalers. Your doctor will work out how much Xolair your child needs and how often it needs to be given. This will depend on your child's weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in his/her blood.

Children (6 to 11 years of age) are not expected to self-administer Xolair. However, if considered appropriate by their doctor, a caregiver may give them their Xolair injection after proper training.

Xolair 300 mg pre-filled syringe is not intended for use in children under 12 years of age. Xolair 75 mg pre-filled syringe and Xolair 150 mg pre-filled syringe or Xolair powder and solvent for solution for injection may be used in children 6-11 years of age with allergic asthma.

Chronic rhinosinusitis with nasal polyps

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

Chronic spontaneous urticaria (CSU)

Xolair can be used in adolescents aged 12 years of age and older, who are already receiving antihistamines but whose CSU symptoms are not well controlled by these medicines. The dose for adolescents aged 12 years and above is the same as for adults.

If a dose of Xolair is missed

If you have missed an appointment, contact your doctor or hospital as soon as possible to re-schedule it.

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

If you stop treatment with Xolair

Do not stop treatment with Xolair unless your doctor tells you to. Interrupting or stopping the treatment with Xolair may cause your symptoms to come back.

However, if you are being treated for CSU, your doctor may stop Xolair treatment from time to time so that your symptoms can be assessed. Follow your doctor's instructions.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects caused by Xolair are usually mild to moderate but can occasionally be serious.

Serious side effects:

Seek medical attention immediately if you notice any signs of the following side effects:

Rare (may affect up to 1 in 1 000 people)

- Severe allergic reactions (including anaphylaxis). Symptoms may include rash, itching or hives on the skin, swelling of the face, lips, tongue, larynx (voice box), windpipe or other parts of the body, fast heartbeat, dizziness and light-headedness, confusion, shortness of breath, wheezing or trouble breathing, blue skin or lips, collapsing and losing consciousness. 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 use of Xolair.
- Systemic lupus erythematosus (SLE). Symptoms may include muscle pain, joint pain and swelling, rash, fever, weight loss, and fatigue.

Not known (frequency cannot be estimated from the available data)

- Churg-Strauss syndrome or hypereosinophilic syndrome. Symptoms may include one or more of the following: swelling, pain or rash around blood or lymph vessels, high level of a specific type of white blood cells (marked eosinophilia), worsening problems with breathing, nasal congestion, heart problems, pain, numbness, tingling in the arms and legs.
- Low blood platelet count with symptoms such as bleeding or bruising more easily than normal.
- Serum sickness. Symptoms may include one or more of the following: joint pain with or without swelling or stiffness, rash, fever, swollen lymph nodes, muscle pain.

Other side effects include:

Very common (may affect more than 1 in 10 people)

- fever (in children)

Common (may affect up to 1 in 10 people)

- reactions at the injection site including pain, swelling, itching and redness
- pain in the upper part of the tummy
- headache (very common in children)
- upper respiratory tract infection, such as inflammation of the pharynx and common cold
- feeling of pressure or pain in the cheeks and forehead (sinusitis, sinus headache)
- pain in joints (arthralgia)
- feeling dizzy

Uncommon (may affect up to 1 in 100 people)

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

Rare (may affect up to 1 in 1 000 people)

- parasitic infection

Not known (frequency cannot be estimated from the available data)

- muscle pain and joint swelling
- hair loss

Reporting of side effects

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

at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xolair

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. The carton containing the pre-filled syringe can be stored for a total time of 48 hours at room temperature (25°C) before use.
- Store in the original package in order to protect from light.
- Store in a refrigerator (2°C – 8°C). Do not freeze.
- Do not use any pack that is damaged or shows signs of tampering.

6. Contents of the pack and other information

What Xolair contains

- The active substance is omalizumab.
 - One syringe of 1 ml solution contains 150 mg omalizumab.
 - One syringe of 2 ml solution contains 300 mg omalizumab.
- The other ingredients are arginine hydrochloride, histidine hydrochloride monohydrate, histidine, Polysorbate 20 and water for injections.

What Xolair looks like and contents of the pack

Xolair solution for injection is supplied as a clear to slightly opalescent, colourless to pale brownish-yellow solution in a pre-filled syringe.

Xolair 150 mg solution for injection in pre-filled syringe with 27-gauge staked needle and purple plunger is supplied in packs containing 1 pre-filled syringe, and in multipacks containing 3 (3 x 1) or 6 (6 x 1) pre-filled syringes.

Xolair 300 mg solution for injection in pre-filled syringe is supplied in packs containing 1 pre-filled syringe, and in multipacks containing 3 (3 x 1) or 6 (6 x 1) pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novartis Pharmaceuticals UK Limited
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London
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United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

Novartis Pharmaceuticals UK Ltd.
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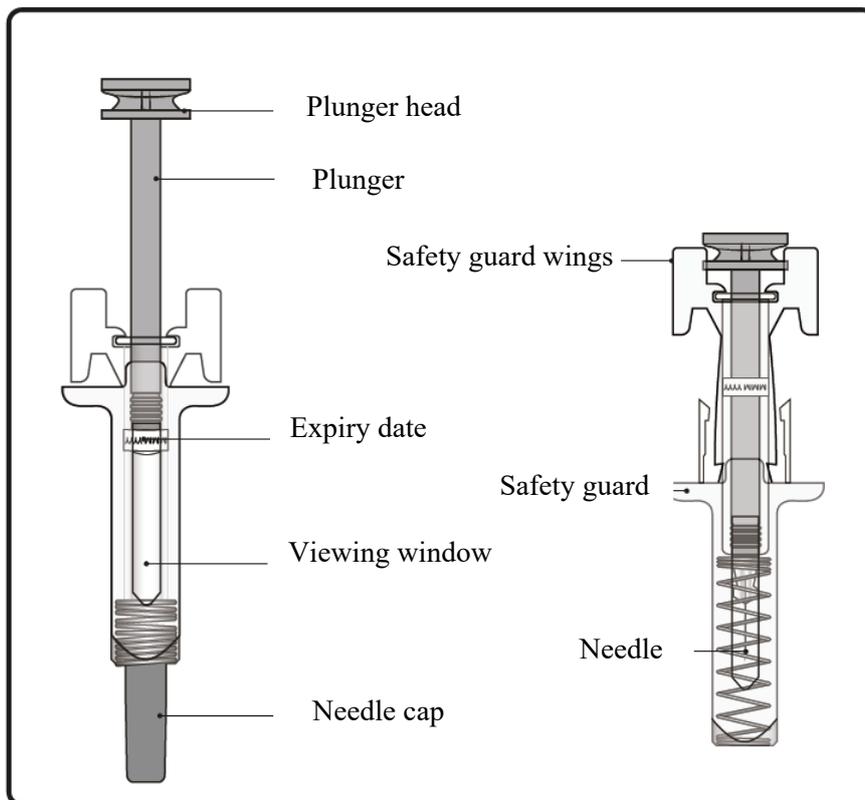
INSTRUCTIONS FOR USE OF XOLAIR PRE-FILLED SYRINGE

These “Instructions for Use” contain 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 these “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.
- **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

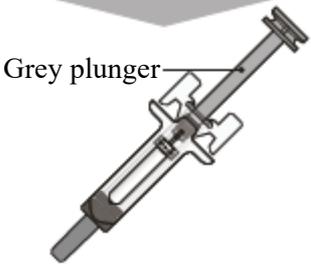
Xolair pre-filled syringes are available in 3 dose strengths (one pre-filled syringe in each carton).

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 grey plunger | |
|--------------------------------|--|--|---|---|--|
| | |  |  |  | |
| DOSE | Pre-filled syringes needed for dose | Blue 75 mg | Purple 150 mg | Grey 300 mg | |
| 75 mg | 1 blue |  | | | |
| 150 mg | 1 purple | |  | | |
| 225 mg | 1 blue + 1 purple |  |  | | |
| 300 mg (ages 12 and up) | 1 grey | | |  | |
| 300 mg (children under age 12) | 2 purple | |  | | |
| 375 mg (ages 12 and up) | 1 blue + 1 grey |  | |  | |
| 375 mg (children under age 12) | 1 blue + 2 purple |  |  | | |
| 450 mg (ages 12 and up) | 1 purple + 1 grey | |  |  | |
| 450 mg (children under age 12) | 3 purple | |  | | |
| 525 mg (ages 12 and up) | 1 blue + 1 purple + 1 grey |  |  |  | |
| 525 mg (children under age 12) | 1 blue + 3 purple |  |  | | |
| 600 mg (ages 12 and up) | 2 grey | | |  | |
| 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

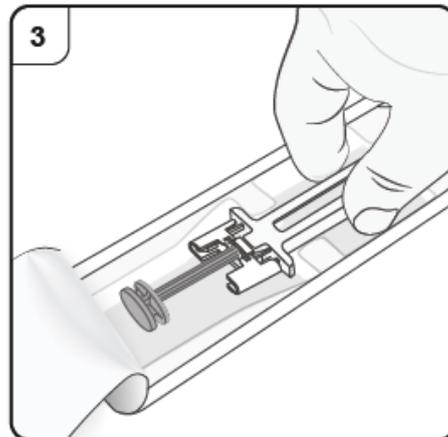
You will need the following supplies (not included in the carton):

- 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.

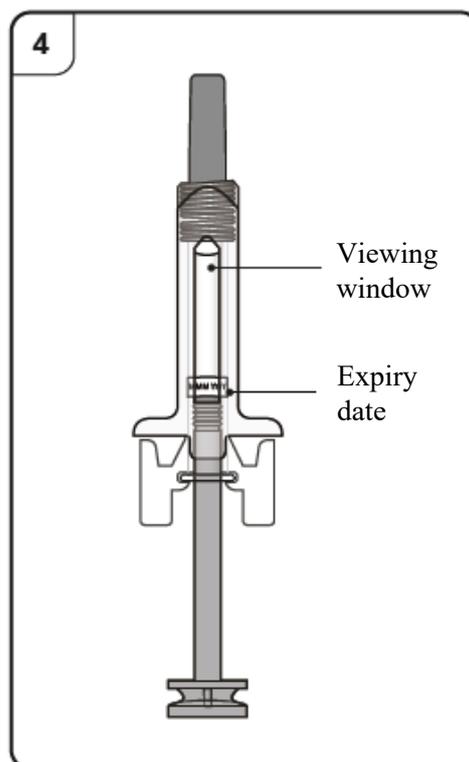


Step 4. Inspect the pre-filled syringe

Look through the viewing window of the pre-filled syringe. The liquid inside should be clear to slightly cloudy. Its colour may vary from colourless 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.

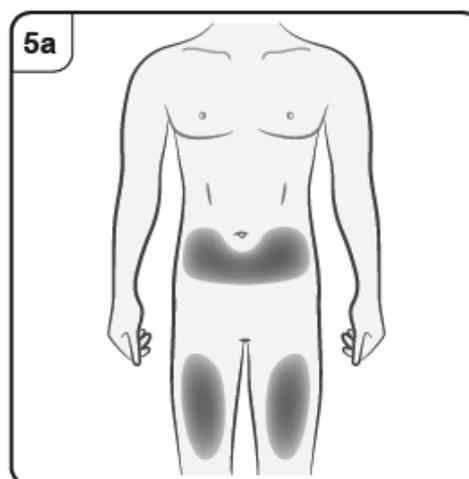


Step 5. Choose injection site

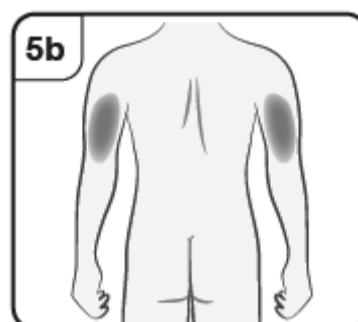
You should inject into the front of the thighs or the lower stomach area but not the area 5 cm around the belly button.

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.

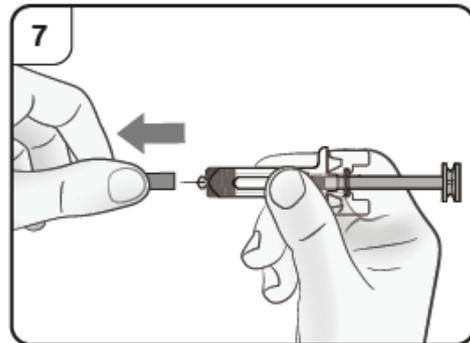
Do not touch or blow on the cleaned skin before injecting.

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.

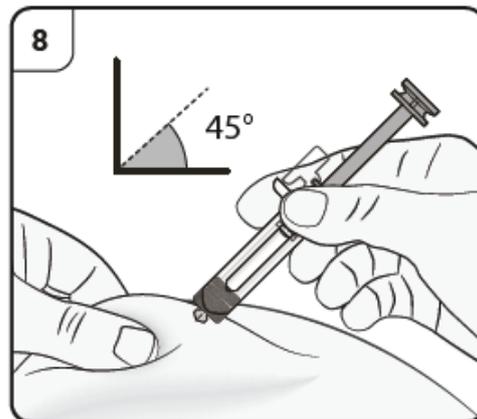
Throw away the needle cap.



Step 8. Insert needle

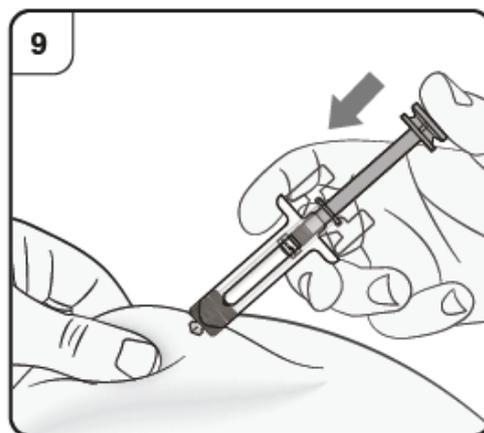
Gently pinch the skin at the injection site and hold the pinch throughout the injection. With the other hand insert the needle into the skin at an angle of approximately 45 degrees as shown.

Do not press the plunger while inserting the needle.



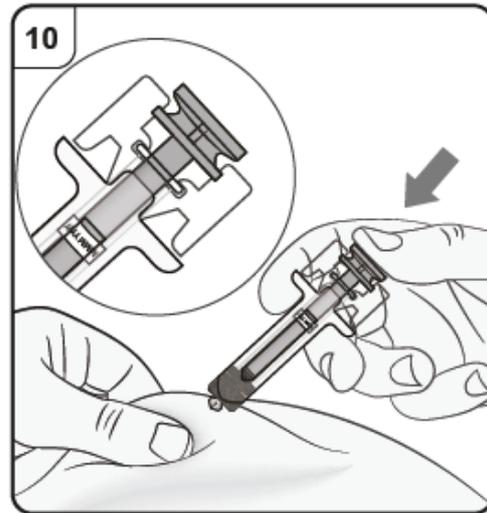
Step 9. Start injection

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 automatically covered by the safety guard. Remove the pre-filled syringe from the injection site and release the pinch.

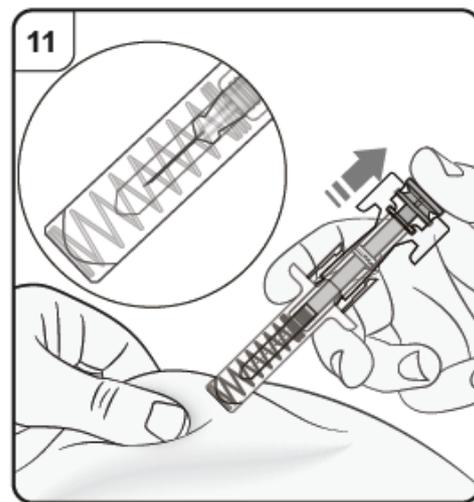
There may be a small amount of blood at the injection site. You can press a cotton ball or gauze pad over the injection site until any bleeding stops. **Do not** rub the injection site. If needed, cover the injection site with a small adhesive plaster.

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 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.