Package leaflet: Information for the user

Nucala 100 mg solution for injection in pre-filled pen

mepolizumab

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.
- 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 Nucala is and what it is used for
2. What you need to know before you use Nucala
3. How to use Nucala
4. Possible side effects
5. How to store Nucala
6. Contents of the pack and other information
7. Step-by-step instructions for use

1. What Nucala is and what it is used for

Nucala contains the active substance **mepolizumab,** a *monoclonal antibody*, a type of protein designed to recognise a specific target substance in the body. It is used to treat **severe asthma** and **EGPA** (Eosinophilic Granulomatosis with Polyangiitis) in adults, adolescents and children aged 6 years and older. It is also used to treat **CRSwNP** (Chronic Rhinosinusitis with Nasal Polyps) and **HES** (Hypereosinophilic syndrome) in adults.

Mepolizumab, the active substance in Nucala, blocks a protein called *interleukin-5*. By blocking the action of this protein, it limits the production of eosinophils from the bone marrow and lowers the number of eosinophils in the bloodstream and the lungs.

Severe eosinophilic asthma

Some people with severe asthma have too many *eosinophils* (a type of white blood cell) in the blood and lungs. This condition is called *eosinophilic asthma* – the type of asthma Nucala can treat.

Nucala can reduce your number of asthma attacks, if you or your child are already using medicines such as high dose inhalers, but your asthma is not well controlled by these medicines.
If you are taking medicines called *oral corticosteroids,* Nucala can also help reduce the daily dose you need to control your asthma.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

CRSwNP is a condition in which people have too many *eosinophils* (a type of white blood cell) in the blood, and tissue lining the nose and sinuses. This can cause symptoms such as a blocked nose and loss of smell, and soft jelly-like growths (called nasal polyps) to form inside the nose.

Nucala reduces the number of eosinophils in the blood and can reduce the size of your polyps, relieves your nasal congestion and helps prevent surgery for nasal polyps.
Nucala can also help reduce the need for *oral corticosteroids* to control your symptoms.

Eosinophilic granulomatosis with polyangiitis (EGPA)

EGPA is a condition where people have too many *eosinophils* (a type of white blood cell) in the blood and tissues and also have a form of *vasculitis*. This means there is inflammation of the blood vessels. This condition most commonly affects the lungs and sinuses but often affects other organs such as the skin, heart and kidneys.

Nucala can control and delay a flare-up of these EGPA symptoms. This medicine can also help reduce the daily dose of *oral corticosteroids* you need to control your symptoms.

Hypereosinophilic syndrome (HES)

Hypereosinophilic syndrome (HES) is a condition in which there are a high number of *eosinophils* (a type of blood cell) in the blood. These cells can damage organs in the body, particularly the heart, lungs, nerves and skin**.**
Nucala helps reduce your symptoms and prevents flares. If you are taking medicines often referred to as *oral corticosteroids,* Nucala can also help reduce the daily dose you need to control your HES symptoms/flares.

2. What you need to know before you use Nucala

Do not use Nucala:
- if you are **allergic** to mepolizumab or any of the other ingredients of this medicine (listed in section 6).

➔ **Check with your doctor** if you think this applies to you.

Warnings and precautions
Talk to your doctor before using this medicine.

Worsening asthma
Some people get asthma-related side effects, or their asthma may become worse, during treatment with Nucala.

➔ **Tell your doctor or nurse** if your asthma remains uncontrolled, or gets worse, after you start Nucala treatment.

Allergic and injection site reactions
Medicines of this type *(monoclonal antibodies)* can cause severe allergic reactions when injected into the body (see section 4, 'Possible side effects').

If you may have had a similar reaction to any injection or medicine:

➔ **Tell your doctor** before you are given Nucala.

Parasitic infections

Nucala may weaken your resistance to infections caused by parasites. If you already have a parasitic infection; it should be treated before you start treatment with Nucala. If you live in a region where these infections are common or if you are travelling to such a region:

➔ **Check with your doctor** if you think any of these may apply to you.

Children and adolescents

Severe eosinophilic asthma

The pre-filled pen is not intended for use in **children below 12 years of age** for the treatment of severe eosinophilic asthma.

For children aged 6-11 years, contact your doctor who will prescribe the recommended dose of Nucala which will be administered by a nurse or doctor.

CRSwNP

This medicine is not intended for use in **children or adolescents below 18 years of age** for the treatment of CRSwNP.

EGPA

This medicine is not intended for use in **children below 6 years of age** for the treatment of EGPA.

HES

This medicine is not intended for use in **adolescents or children below 18 years of age** for the treatment of HES.

Other medicines and Nucala
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Other medicines for asthma, CRSwNP, EGPA or HES

✘ **Don't suddenly stop taking** your existing medicines for your asthma, CRSwNP, EGPA or HES once you have started Nucala. These medicines (especially ones called *oral corticosteroids*) must be stopped gradually, under the direct supervision of your doctor and dependent on your response to Nucala.

Pregnancy and breast-feeding
If you are pregnant, if you think you may be pregnant or are planning to have a baby, **ask your doctor for advice** before using this medicine.

It is not known whether the ingredients of Nucala can pass into breast milk. **If you are breast-feeding, you must check with your doctor** before you use Nucala.

Driving and using machines
The possible side effects of Nucala are unlikely to affect your ability to drive or use machines.

Nucala contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 100 mg dose, i.e., that is to say essentially "sodium-free".

3. How to use Nucala

Nucala is given by injection just under the skin (*subcutaneous injection*).

Your doctor or nurse will decide if you or your caregiver can inject Nucala. If appropriate, they will then provide training to show you or your caregiver the correct way to use Nucala.

Nucala must be given to children aged 6 to 11 years by a doctor, nurse or trained caregiver.

Severe eosinophilic asthma

The recommended dose for adults and adolescents aged 12 years and older is 100 mg. You will have 1 injection every four weeks.

CRSwNP

The recommended dose for adults is 100 mg. You will have 1 injection every four weeks.

EGPA

The recommended dose for adults and adolescents aged 12 years and older is 300 mg. You will have 3 injections every four weeks.

Children aged 6 to 11 years old

Children weighing 40 kg or more:
The recommended dose is 200 mg. You will have 2 injections every four weeks.

Children weighing less than 40 kg:
The recommended dose is 100 mg. You will have 1 injection every four weeks.

The injection sites should be at least 5 cm apart.

HES

The recommended dose for adults is 300 mg. You will have 3 injections every four weeks.

The injection sites should be at least 5 cm apart.

Instructions for using the pre-filled pen are given on the other side of this leaflet.

If you use more Nucala than you should
If you think you have injected too much Nucala, **contact your doctor** for advice.

If a dose of Nucala is missed
You or your caregiver should inject the next dose of Nucala as soon as you remember. If you do not notice that you have missed a dose until it is already time for your next dose, then just inject the next dose as planned. If you are not sure what to do, ask your doctor, pharmacist or nurse.

Stopping treatment with Nucala
Do not stop injections of Nucala unless your doctor advises you to. Interrupting or stopping the treatment with Nucala may cause your symptoms and attacks to come back.

If your symptoms get worse while receiving injections of Nucala
➔ **Call your doctor**.

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 Nucala are usually mild to moderate but can occasionally be serious.

Allergic reactions
Some people may have allergic or allergic-like reactions. These reactions may be common (they can affect **up to 1 in 10 people).** They usually occur within minutes to hours after the injection, but sometimes symptoms can start up to several days later.

Symptoms can include:
- chest tightness, cough, difficulty breathing
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)
- swelling of eyelids, face, lips, tongue or mouth
- hives
- rash

➔ **Seek medical attention immediately** if you think you (or your child) may be having a reaction.

If you may have had a similar reaction to any injection or medicine:
➔ **Tell your doctor** before you (or your child) are given Nucala.

Other side effects include:

Very common:
may affect more than 1 in 10 people
- headache

Common:
may affect up to 1 in 10 people
- chest infection - symptoms of which may include cough and fever (high temperature)
- urinary tract infection (blood in urine, painful and frequent urination, fever, pain in lower back)
- upper abdominal pain (stomach pain or discomfort in the upper area of the stomach)
- fever (high temperature)
- eczema (itchy red patches on the skin)
- injection-site reaction (pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given)
- back pain
- pharyngitis (sore throat)
- nasal congestion (stuffy nose)

Rare:
may affect up to 1 in 1,000 people
- severe allergic reactions (*anaphylaxis*)

➔ **Tell your doctor or a nurse immediately** if you get any of these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme Website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Nucala

Keep this medicine out of the sight and reach of children.

Do not use Nucala after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Store in the original package in order to protect from light.

The Nucala pre-filled pen can be removed from the refrigerator and kept in its unopened carton for up to 7 days at room temperature (up to 30°C), when protected from light. Discard if left out of the refrigerator for more than 7 days.

6. Contents of the pack and other information

What Nucala contains
The active substance is mepolizumab.

Each 1 mL pre-filled pen contains 100 mg of mepolizumab.
The other ingredients are sucrose, sodium phosphate dibasic heptahydrate, citric acid monohydrate, polysorbate 80, disodium edetate, water for injections.

What Nucala looks like and contents of the pack

Nucala is supplied as a 1 mL clear to opalescent, colourless to pale yellow to pale brown solution in a single use pre-filled pen.

Nucala is available in a pack containing 1 pre-filled pen, or in a multipack comprised of 3 x 1 pre-filled pens or 9 x 1 pre-filled pens.

Marketing Authorisation Holder
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TW8 9GS
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Manufacturer

GlaxoSmithKline Manufacturing S.P.A
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Or

Glaxo Operations UK Ltd
Harmire Road
Barnard Castle
County Durham, DL12 8DT
United Kingdom

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name **Nucala 100mg solution for injection in pre-filled pen**
Reference number 19494/0290

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 11/2022

7. Step by step instructions for using the pre-filled pen

Administer once every four weeks.

Follow these instructions on how to use the pre-filled pen. Failure to follow these instructions may affect proper function of the pre-filled pen. You should also receive training on how to use the pre-filled pen. Nucala pre-filled pen is for use **under the skin only** (subcutaneous).

How to store Nucala

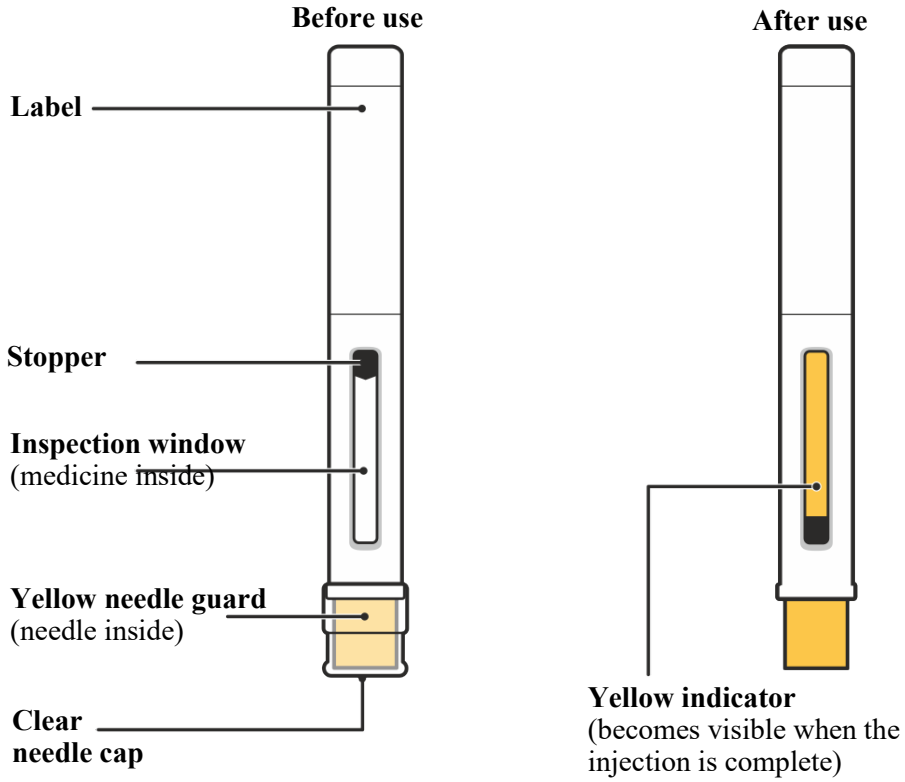
- Keep refrigerated before use.
- Do not freeze
- Keep the pre-filled pen in the carton to protect from light.
- Keep out of the sight and reach of children.
- If necessary, the pre-filled pen may be kept at room temperature, up to 30°C, for no more than 7 days, when stored in the original carton. Safely, throw the pen away if it has been kept out of the refrigerator for more than 7 days.
- Do not store it above 30°C.

Before you use Nucala

The pre-filled pen should be used only once and then discarded.

- **Do not** share your Nucala pre-filled pen with another person.
- **Do not** shake the pen.
- **Do not** use the pen if dropped onto a hard surface.
- **Do not** use the pen if it appears damaged.
- **Do not** remove the needle cap until just before your injection.

Know your pre-filled pen



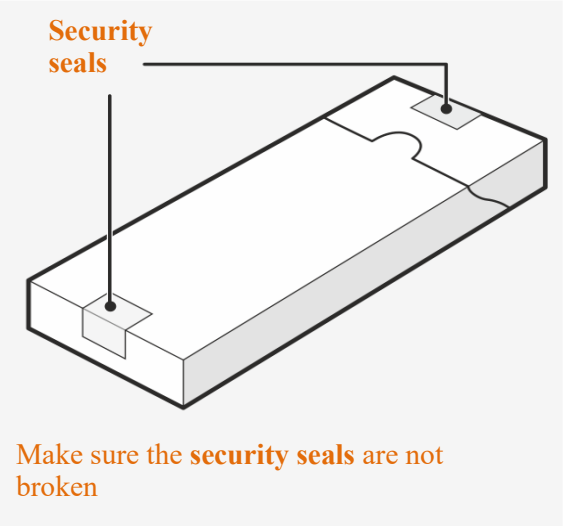
Prepare

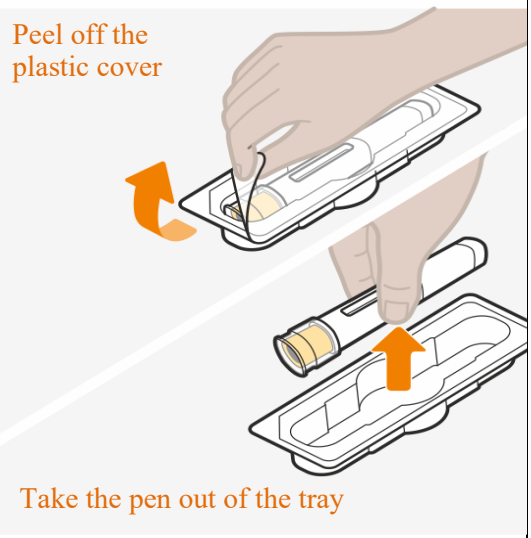
1.Get ready what you need

Find a comfortable, well-lit and clean surface. Make sure you have within reach:

- Nucala pre-filled pen
- Alcohol wipe (not included)
- Gauze pad or cotton wool ball (not included)

2. Take out your pre-filled pen



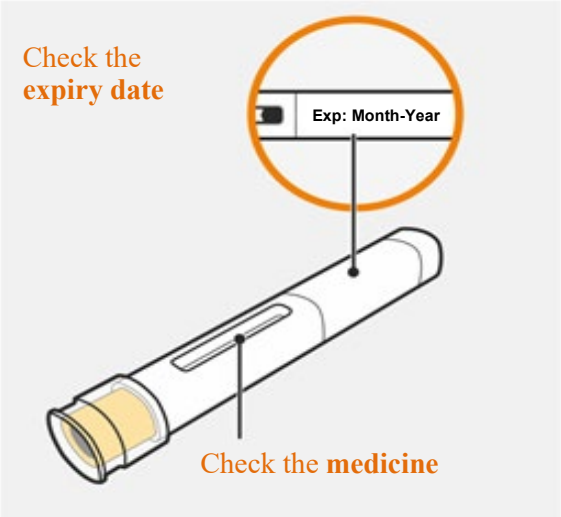


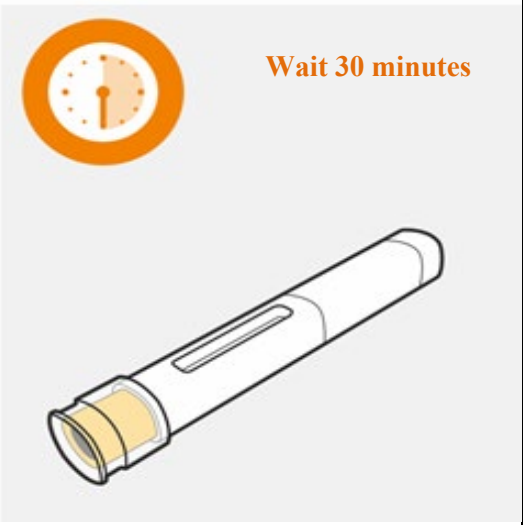
- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel back the film cover from the tray.
- Holding the middle of the pen, carefully take it out of the tray.
- Place the pen on a clean, flat surface, at room temperature, away from direct sunlight and out of the reach of children.

Do not use the pen if the security seal on the carton is broken.

Do not remove the needle cap at this stage.

3. Inspect and wait 30 minutes before use



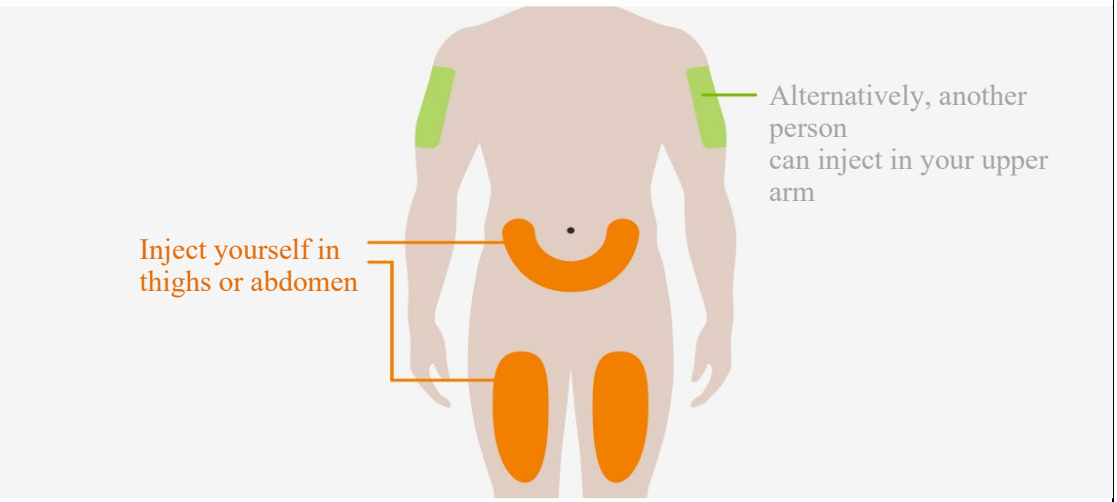


- Check the expiry date on the label of the pen.

- Look in the inspection window to check that the liquid is clear (free from cloudiness or particles) and colourless to pale yellow to pale brown.
- It is normal to see one or more air bubbles.
- Wait 30 minutes (and no more than 8 hours) before use.

Do not use if the expiry date has passed.
Do not warm the pen in a microwave, hot water, or direct sunlight.
Do not inject if the solution looks cloudy or discoloured, or has particles.
Do not use the pen if left out of the carton for more than 8 hours.
Do not remove the needle cap during this step.

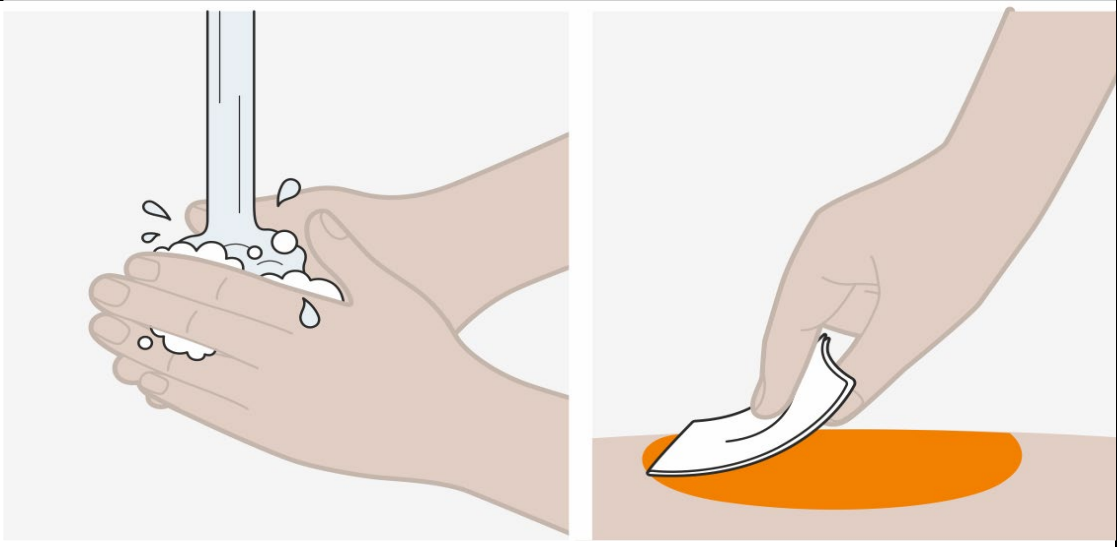
4. Choose your injection site



- You can inject Nucala into your thighs or abdomen.
- If someone else gives you the injection, they can also use your upper arm.
- If you need more than one injection to complete your dose, then leave at least 5 cm between each injection site

Do not inject where your skin is bruised, tender, red or hard.
Do not inject within 5 cm of your navel (belly button).

5. Clean your injection site

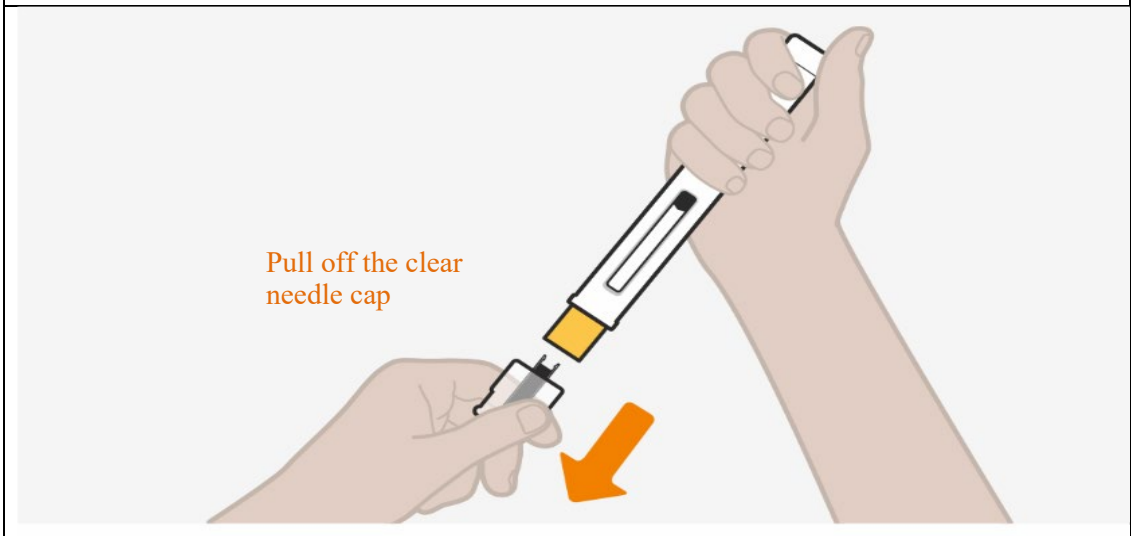


- Wash your hands with soap and water.
- Clean your injection site by wiping the skin with an alcohol wipe and allowing the skin to air dry.

Do not touch your injection site again until you have finished your injection.

Inject

6. Remove the clear needle cap

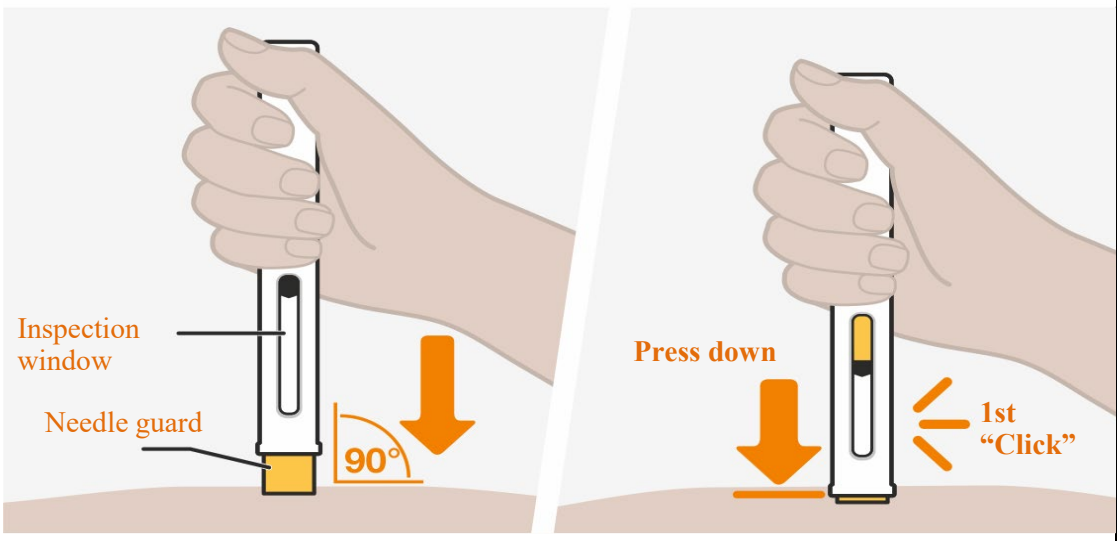


- Remove the clear needle cap from the pen by firmly pulling it straight off.
- Do not worry if you see a drop of liquid at the end of the needle. This is normal.
- Inject straight after removing the needle cap, and **always** within 5 minutes.

Do not touch the yellow needle guard with your fingers. This could activate the pen too soon and may cause a needle injury.

After removal, **do not** put the needle cap back onto the pen, as it may accidentally start the injection.

7. Start your injection

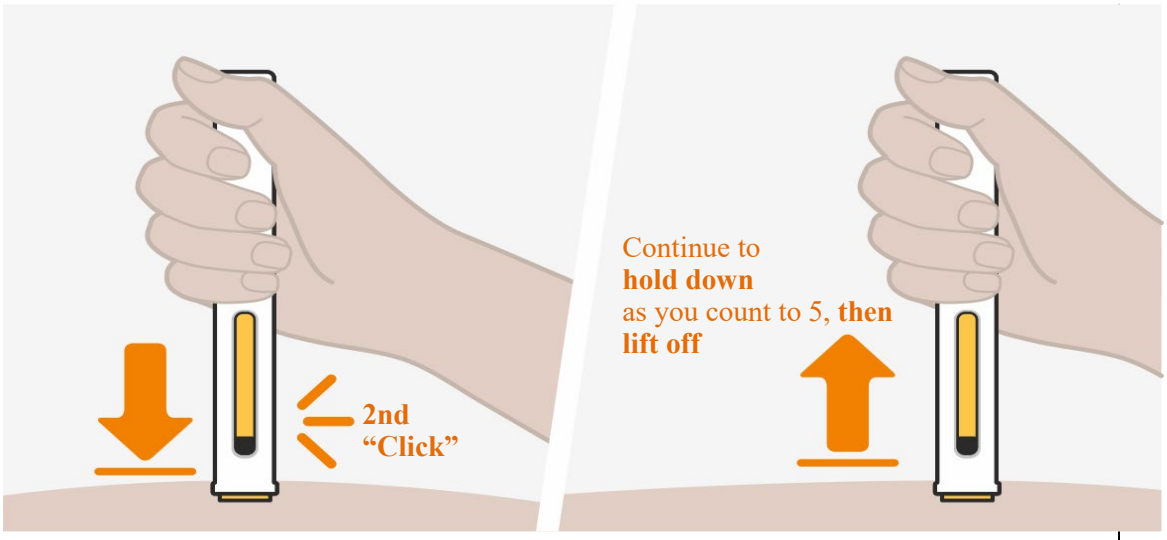


- Hold the pen with its inspection window facing towards you, so you can see it, and with the yellow needle guard facing down.
- Place the pen straight onto your injection site with the yellow needle guard flat against the surface of your skin, as shown.
- To start your injection, push the pen down all the way and keep it held down against your skin. The yellow needle guard will slide up into the pen.
- You should hear the 1st "click" to tell you your injection has started.
- The yellow indicator will move down through the inspection window as you receive your dose.

Do not lift the pen from your skin at this stage, as that may mean you don't get your full dose of medicine. Your injection may take up to 15 seconds to complete.

Do not use the pen if the yellow needle guard doesn't slide up as described. Dispose of it (see Step 9), and start again with a new pen.

8. Hold the pen in place to complete your injection



- Continue to hold the pen down until you hear the 2nd "click", and the stopper and yellow indicator have stopped moving and fill the inspection window.
- Continue to hold the pen in place while you count to 5. Then lift the pen away from your skin.
- If you do **not** hear the 2nd "click":
  - –Check that the inspection window is filled with the yellow indicator.
  - –If you are not sure, hold the pen down for another 15 seconds to make sure the injection is complete.

Do not lift the pen until you are sure you have completed your injection.

- You may notice a small drop of blood at the injection site. This is normal. Press a cotton wool ball or gauze on the area for a few moments if necessary.

Do not rub your injection site.

Dispose

9. Dispose of the used pen

- Dispose of the used pen and needle cap according to local requirements. Ask your doctor or pharmacist for advice if necessary.
- **Keep your used pens and needle caps out of the sight and reach of children.**