



PATIENT INFORMATION LEAFLET

NUCALA 100 mg in 1 mL pre-filled pen (auto-injector) NUCALA 100 mg in 1 mL pre-filled syringe (safety syringe)

Mepolizumab

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any questions, ask your doctor or nurse.

If you notice any side effects that bother you or do not go away, please tell your doctor or nurse.

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 in adults and adolescents and in EGPA (Eosinophilic Granulomatosis with Polyangiitis) in adults, adolescents and children 6 years of age and **over**.

Mepolizumab, the active substance in NUCALA lowers the number of *eosinophils* (**a type of white blood cell**) in the bloodstream, lungs and tissues.

Severe Eosinophilic Asthma

Some people with severe asthma have too many *eosinophils* in the blood and lungs. This condition is called *eosinophilic asthma* – the type of asthma NUCALA can treat.

If your asthma is not well controlled by your existing treatment, NUCALA can reduce your number of asthma attacks.

If you are taking medicines called *oral corticosteroids*, NUCALA can also help reduce the daily dose you need to control your asthma.

EGPA (Eosinophilic Granulomatosis with Polyangiitis)

EGPA is a condition where people have too many eosinophils in the blood and tissues and also have inflammation of the blood vessels (vasculitis). EGPA most commonly affects the lungs and sinuses but often affects other organs including the skin, heart, kidneys, nerves or bowels.



NUCALA can reduce the number of eosinophils in the blood and can reduce symptoms and delay a flare-up of these symptoms in people who are already taking corticosteroids.

NUCALA can also help reduce the daily dose of corticosteroids you need to control your symptoms.

2. Before you are given NUCALA

You must not receive 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.

Take special care with NUCALA

NUCALA should not be used to treat sudden breathing problems that may occur with 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.

Tell your doctor before you are given NUCALA if you may have had a similar reaction to any injection or medicine.

Parasitic infections

NUCALA may weaken your resistance to infections caused by parasites. If you 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

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

Other medicines and NUCALA

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

Other medicines for asthma or EGPA

- ✘ Don't suddenly stop taking your medicines for your asthma, or EGPA once you have started NUCALA. These medicines (especially ones called 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.

3. How NUCALA is used

Solution for injection in pre-filled pen (auto-injector) or pre-filled syringe (safety syringe) (which can be given either by you, your caregiver or a doctor/nurse).

NUCALA is given by injection under your 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.



You can inject NUCALA under your skin in your stomach area (abdomen) or upper leg (thigh). Your caregiver can also inject NUCALA into your upper arm. You should not give injections into areas where the skin is tender, bruised, red, or hard.

Severe asthma

Adults and adolescents aged 12 years and over

The recommended dose is one 100 mg injection every four weeks.

EGPA

Adults and adolescents aged 12 years and over

The recommended dose for adults and adolescents is 300 mg (three 100 mg injections) every four weeks.

If you need more than one injection to complete your dose, the injection sites should be at least 5 cm apart.

Children aged 6 to 11 years of age

Children weighing 40 kg and over:

The recommended dose is 300 mg (three 100 mg injections) every four weeks.

Children weighing 25 kg and over but less than 40 kg:

The recommended dose is 200 mg (two 100 mg injections) every four weeks.

Children weighing less than 25 kg:

The recommended dose is one 100 mg injection every four weeks.

If a dose of NUCALA is missed

If you or your caregiver forget to give the injection of NUCALA using a pre-filled pen or pre-filled syringe:

You 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.

Don't stop NUCALA without advice



Do not stop injections of NUCALA unless your doctor advises you to. Interrupting or stopping the treatment with NUCALA may cause your symptoms 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

Allergic reactions, which may be severe to NUCALA are rare (they may affect up to 1 in 1000 people).

If you have any of the following symptoms after taking NUCALA:

- skin rash (hives) or redness
- swelling, sometimes of the face or mouth (angioedema)
- becoming very wheezy, coughing or having difficulty in breathing
- suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)

□ Stop using NUCALA and seek medical help immediately

Very common side effects

These may affect **more than 1 in 10** people:

- headache

Common side effects

These 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 side effects

These may affect **up to 1 in 1,000** people:

- allergic reactions which may be severe (e.g. anaphylaxis) (See earlier in **Section 4**).

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

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 refrigerator (2-8°C). Do not freeze.

Store in the original carton to protect from light.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

The pre-filled pen and pre-filled syringe 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.

6. Further information

What NUCALA contains

The active substance is mepolizumab.



Solution for injection in pre-filled pen (auto-injector) and pre-filled syringe (safety syringe)

Each 1 mL pre-filled pen and syringe contains 100 mg mepolizumab.

Other ingredients are:

Sucrose, sodium phosphate dibasic heptahydrate, citric acid monohydrate, polysorbate 80, EDTA disodium dehydrate and Water for injection.

What NUCALA looks like and contents of the pack

Solution for injection in pre-filled pen (auto-injector)

NUCALA is supplied as a clear, colourless to pale yellow to pale brown solution in a 1 mL siliconised, Type I glass syringe with 0.5 inch (12.7 mm), 29 gauge, stainless steel needle assembled as an auto-injector.

NUCALA is available in a pack containing 1 single-use pre-filled pen.

Solution for injection in pre-filled syringe (safety syringe)

NUCALA is supplied as a clear, colourless to pale yellow to pale brown solution in a 1 mL siliconised, Type I glass syringe with 0.5 inch (12.7 mm), 29 gauge, stainless steel needle assembled with a needle guard.

NUCALA is available in a pack containing 1 single-use pre-filled syringe.

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INSTRUCTIONS FOR USE

Solution for injection in pre-filled pen (auto-injector)

NUCALA pre-filled pen (auto-injector)

(*mepolizumab*)

Administer once every 4 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 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.
- Do not store it above 30°C.
- Safely throw it away if it has been removed from the refrigerator and not been used within 7 days.

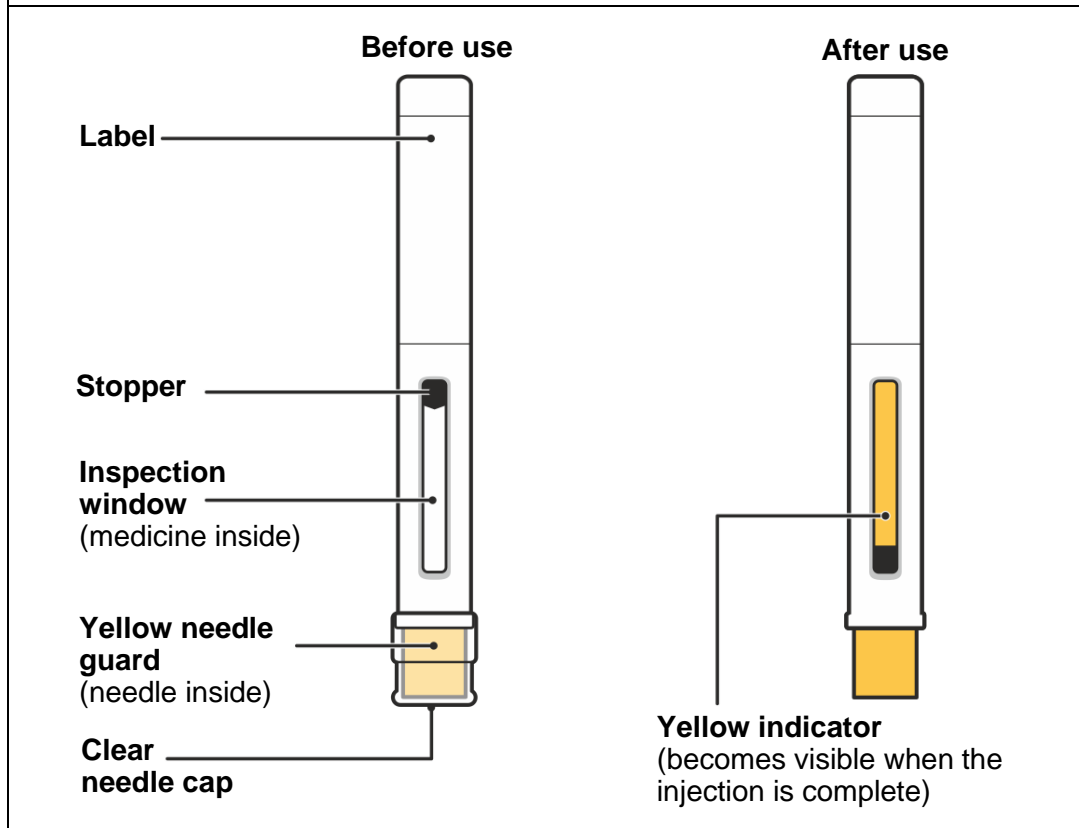
Before you use NUCALA

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

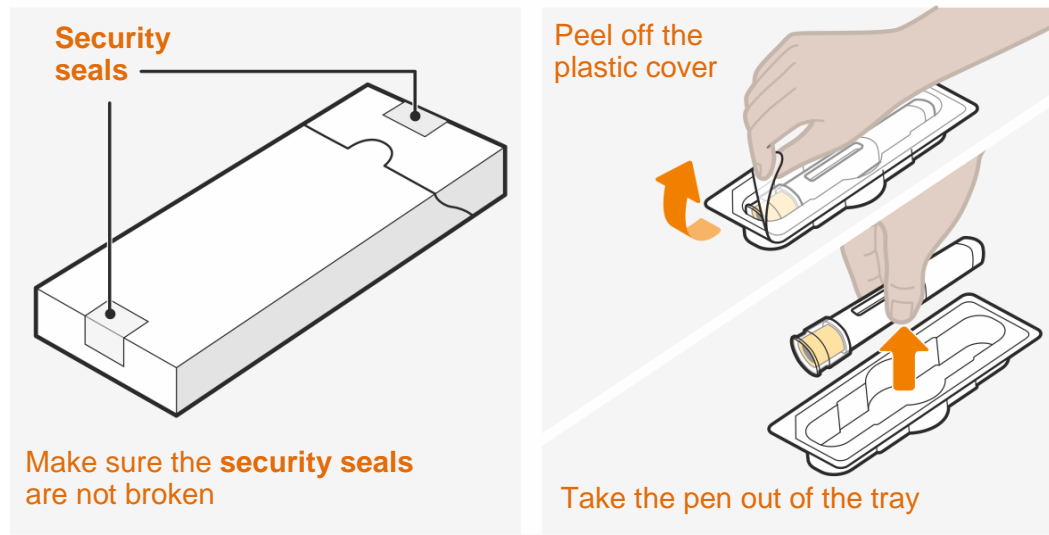
1. Get ready what you need

- 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)

Do not perform the injection if you do not have all these.



2. Take out your pre-filled pen



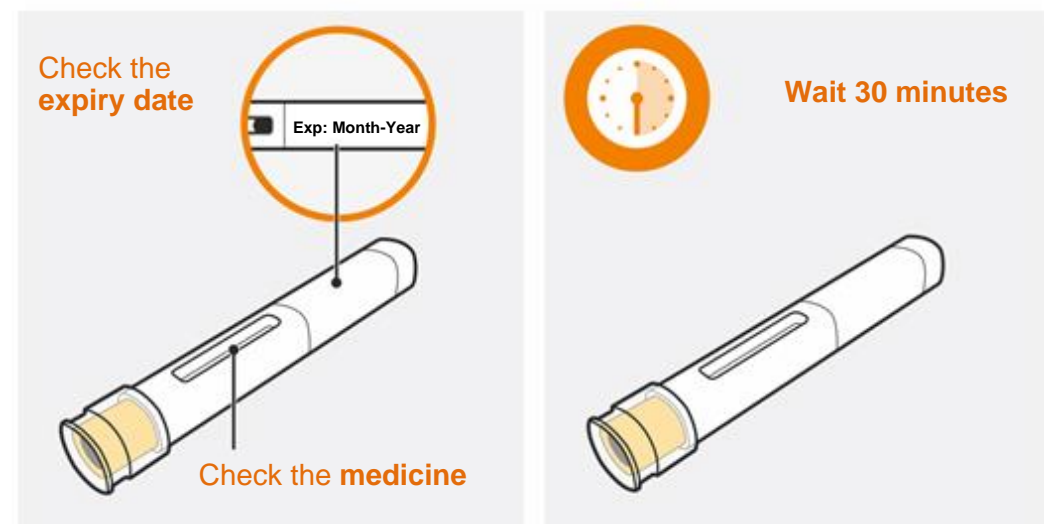
- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel back the film cover from the tray.
- Holding the middle of the pen, carefully take it out of the tray.
- Place the pen on a clean, flat surface, at room temperature, away from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

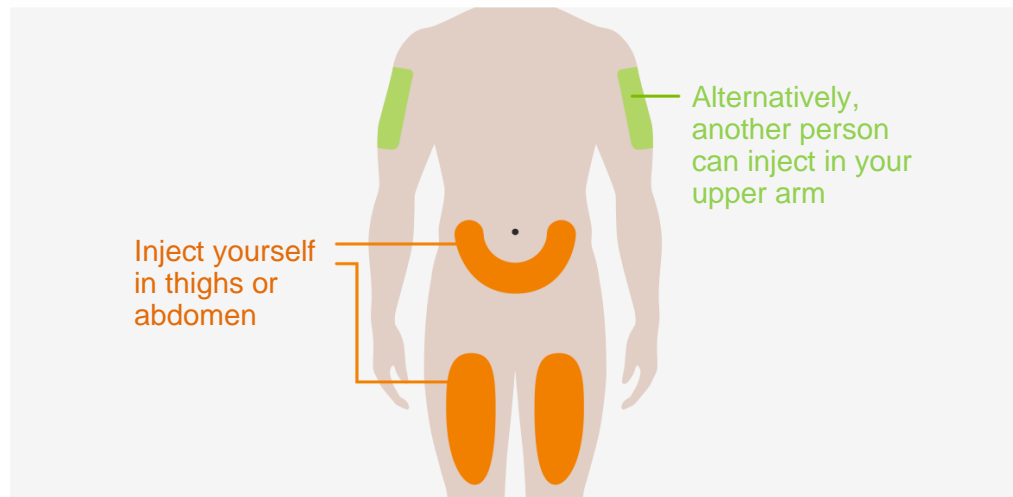
Do not inject if the solution looks cloudy or discoloured, or has particles.

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

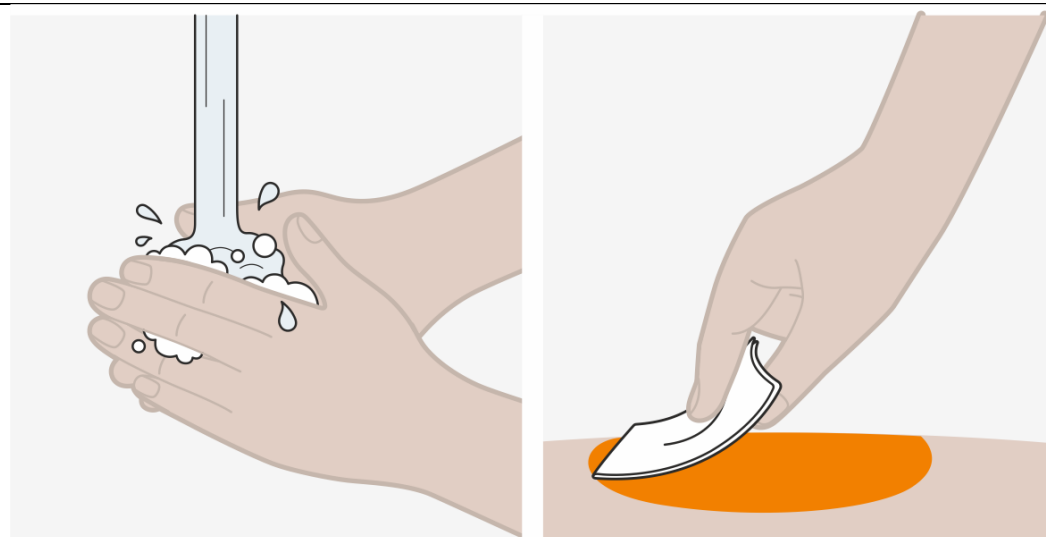


- You can inject NUCALA into your thighs or abdomen.
- If someone else gives you the injection, they can also use your upper arm.
- If you need more than one injection to complete your dose then leave at least 5 cm between each injection site.

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.

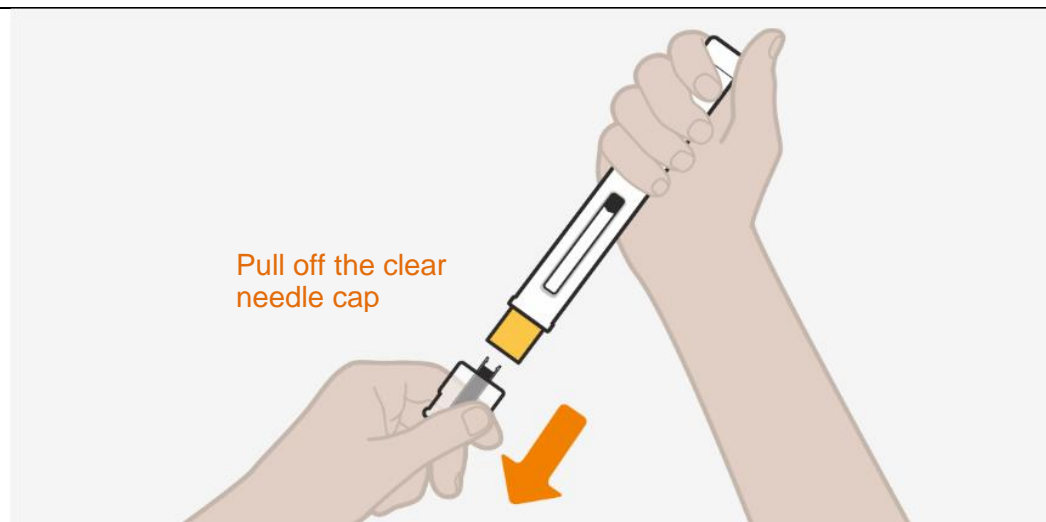


- Clean your injection site by wiping the skin with an alcohol wipe and allowing the skin to air dry.

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

Inject

6. Remove the clear needle cap



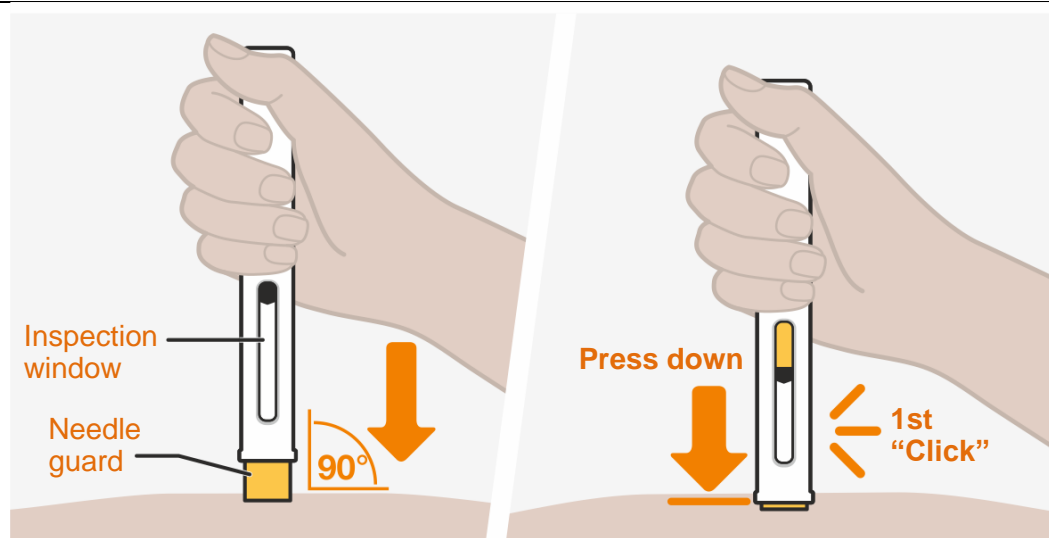
- Remove the clear needle cap from the pen by firmly pulling it straight off.
- Do not worry if you see a drop of liquid at the end of the needle. This is normal.
- Inject straight after removing the needle cap, and always within 5 minutes.

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



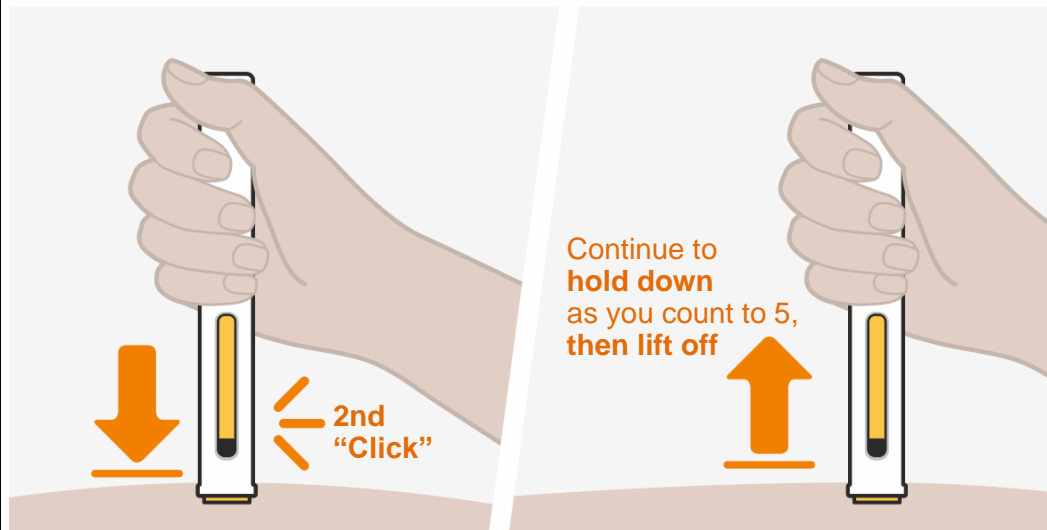
- Hold the pen with its inspection window facing towards you, so you can see it, and with the yellow needle guard facing down.
- Place the pen straight onto your injection site with the yellow needle guard flat against the surface of your skin, as shown.
- To start your injection, push the pen down all 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.



INSTRUCTIONS FOR USE

Solution for injection in pre-filled syringe (Safety syringe)

NUCALA pre-filled syringe (Safety syringe)

(*mepolizumab*)

Administer once every 4 weeks.

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

How to store NUCALA

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

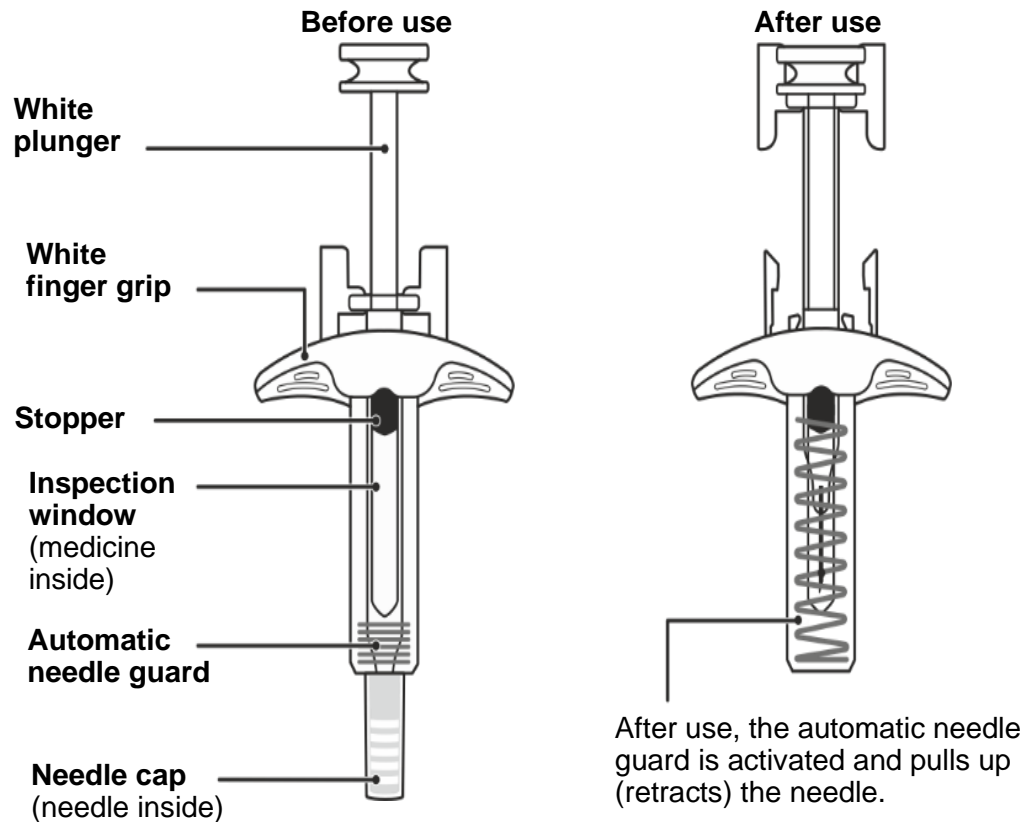
Before you use NUCALA

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

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



Know your pre-filled syringe



Prepare

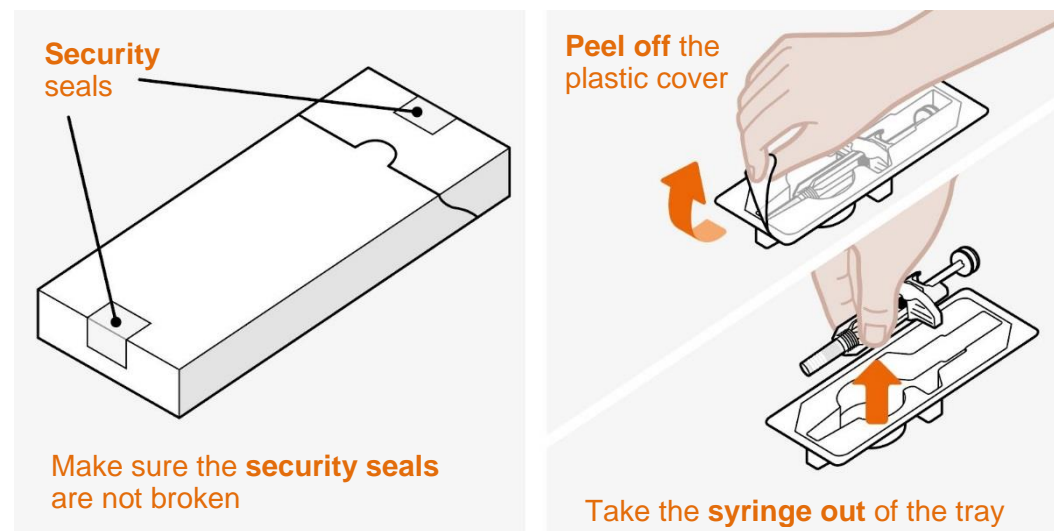
1. Get ready what you need

- Find a comfortable, well-lit and clean surface. Make sure you have within reach:
 - NUCALA pre-filled syringe
 - Alcohol wipe (not included)
 - Gauze pad or cotton wool ball (not included)

Do not perform the injection if you do not have all these.



2. Take out your pre-filled syringe

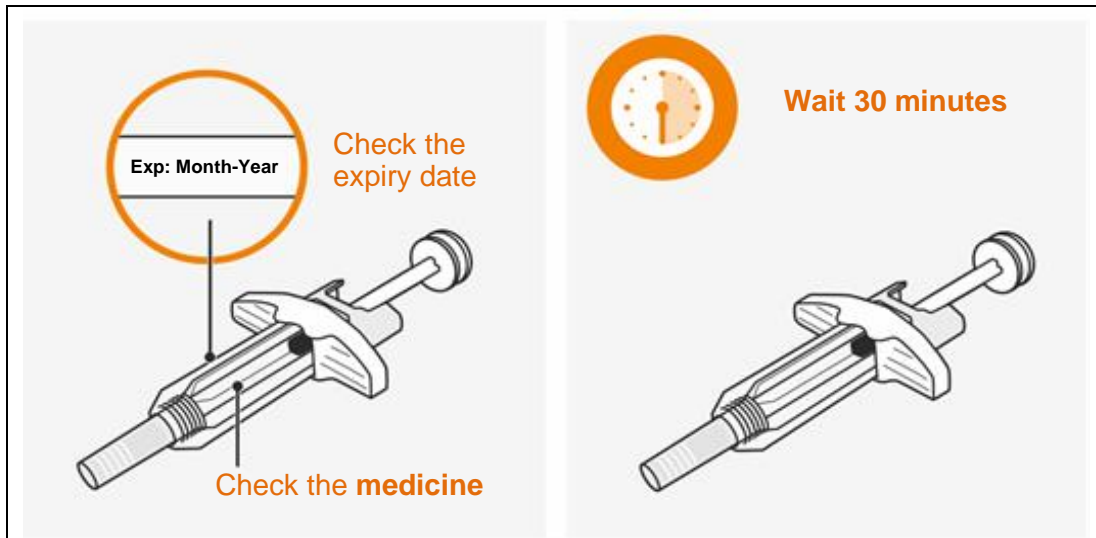


- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel back the film cover from the tray.
- Holding the middle of the syringe, carefully take it out of the tray.
- Place the syringe on a clean, flat surface, at room temperature, away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

Do not use the syringe 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 syringe.
- 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.

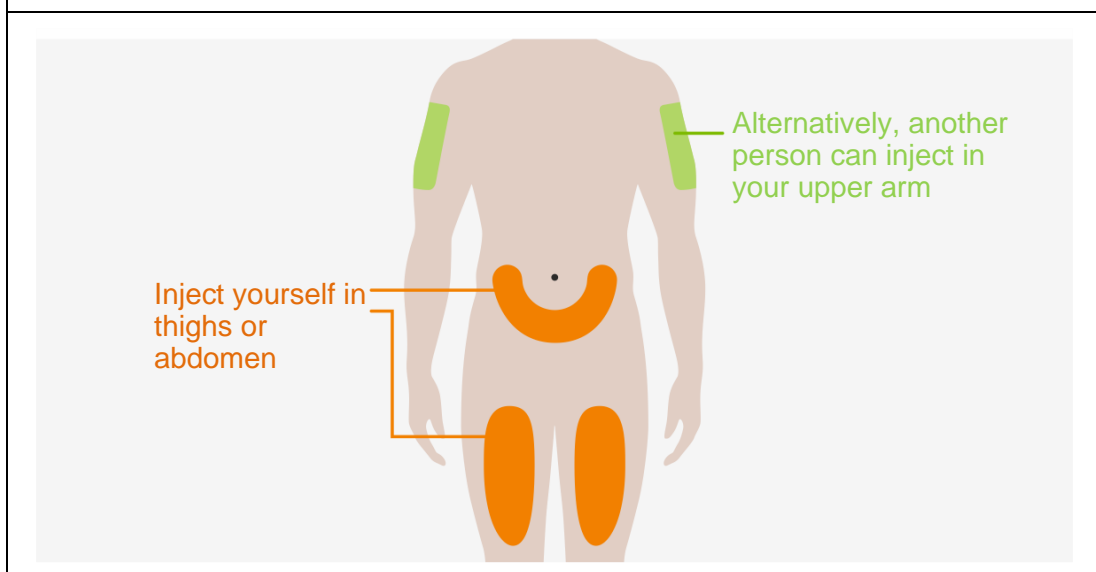
Do not warm the syringe in a microwave, hot water, or direct sunlight.

Do not inject if the solution looks cloudy or discoloured, or has particles.

Do not use the syringe 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



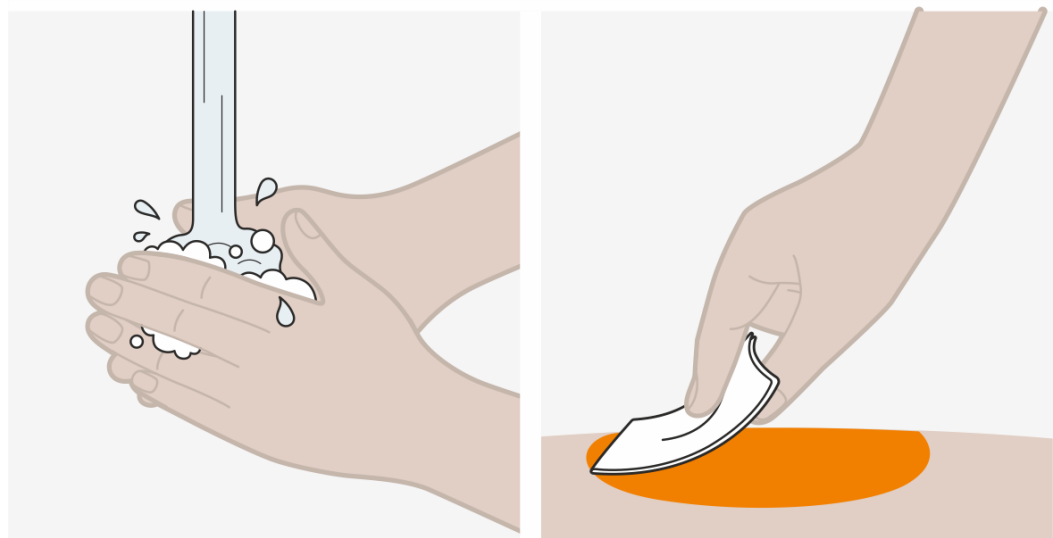


- You can inject NUCALA into your thighs or abdomen.
- If someone else gives you the injection, they can also use your upper arm.
- If you need more than one injection to complete your dose then leave at least 5 cm between each injection site.

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



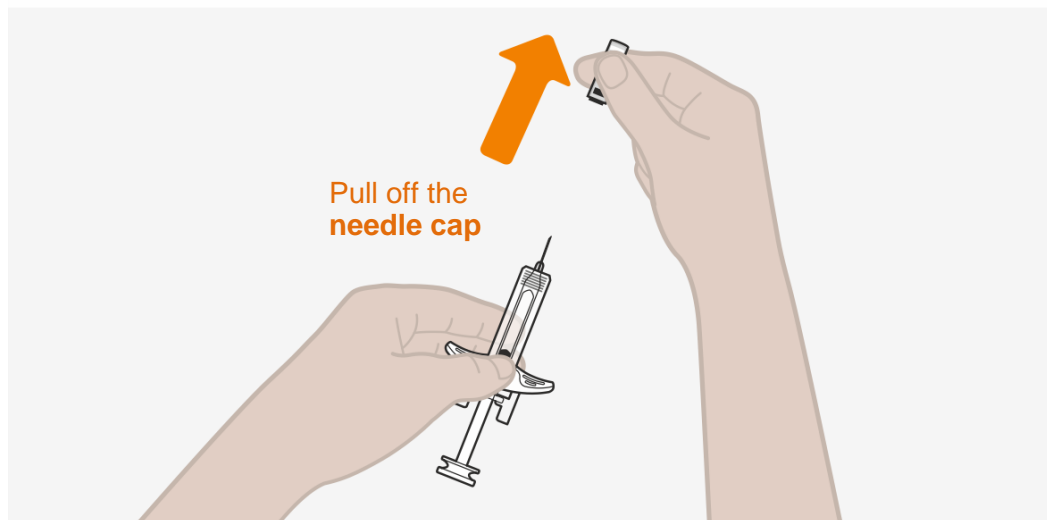
- Wash your hands with soap and water.
- Clean your injection site by wiping the skin with an alcohol wipe and allowing the skin to air dry.

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



Inject

6. Remove the needle cap



- Remove the needle cap from the syringe by firmly pulling it straight off, extending your hand away from the needle end (as shown). You may need to pull the needle cap quite firmly to remove it.
- **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 let the needle touch any surface.

Do not touch the needle.

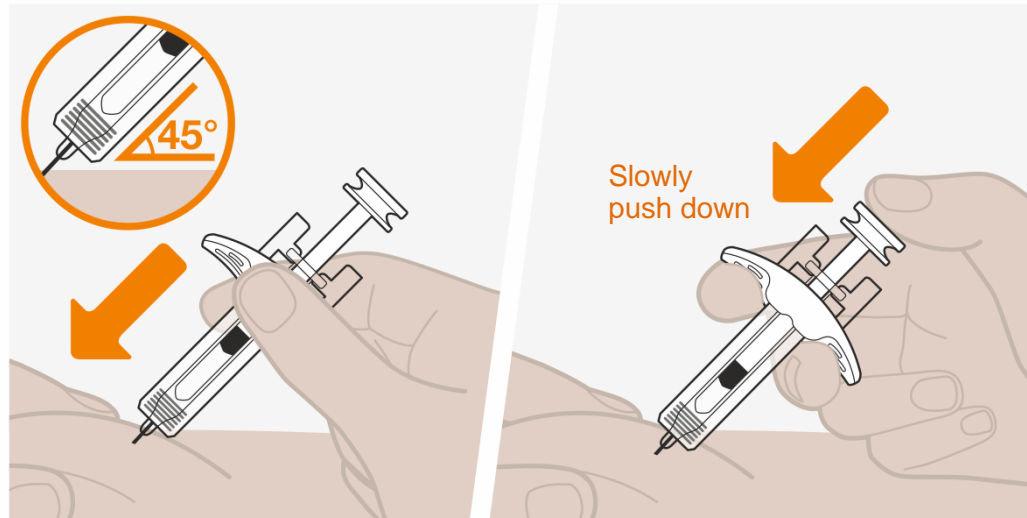
Do not touch the plunger at this stage, as you can accidentally push liquid out and will not receive your full dose.

Do not expel any air bubbles from the syringe.

Do not put the needle cap back onto the syringe. This could cause a needle injury.

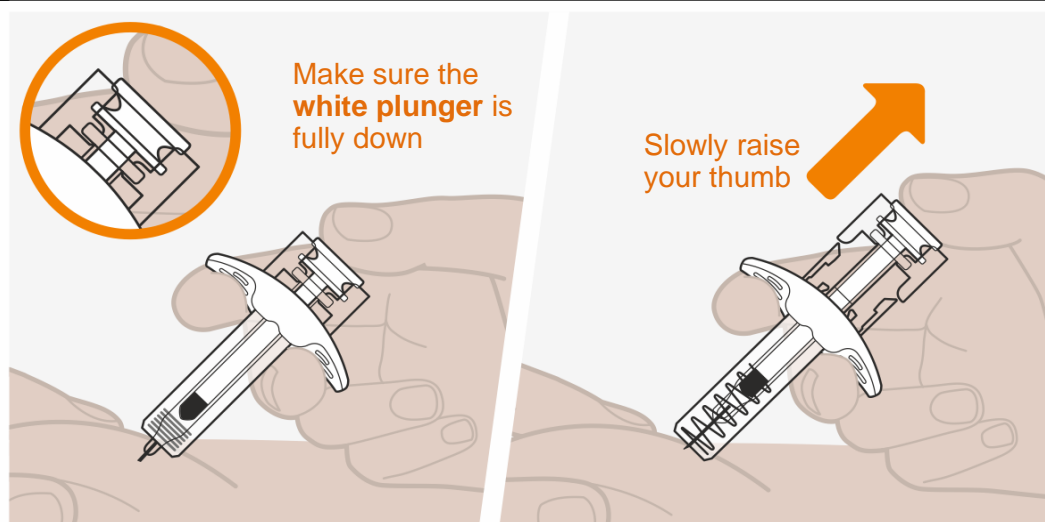


7. Start your injection



- Use your free hand to pinch the skin around your injection site. Keep the skin pinched throughout your injection.
- Insert the entire needle into the pinched skin at a 45° angle, as shown.
- Move your thumb to the plunger and place your fingers on the white finger grip, as shown.
- Slowly push down on the plunger to inject your full dose.

8. Complete your injection



- Make sure the plunger is pushed all the way down, until the stopper reaches the bottom of the syringe and all of the solution is injected.



- Slowly lift your thumb up. This will allow the plunger to come up and the needle to retract (rise up) into the body of the syringe.
- Once complete, release the pinched skin.
 - 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** put the needle cap back onto the syringe.
- **Do not** rub your injection site.

Dispose

9. Dispose of the used syringe

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

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