

NUCALA

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

Australian Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using NUCALA.

This leaflet answers some common questions about NUCALA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NUCALA against the benefits he or she expects it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NUCALA is used for

NUCALA is a medicine which contains the active substance mepolizumab, a monoclonal antibody. This antibody blocks a specific protein called interleukin-5. By blocking the action of interleukin-5, NUCALA limits the production of more eosinophils (a type of white blood cell) from the bone marrow and lowers the number of eosinophils in the bloodstream and the lungs.

NUCALA is used to treat severe eosinophilic asthma or to treat eosinophilic granulomatosis with polyangiitis (EGPA).

Severe eosinophilic asthma

Some people with severe asthma have too many eosinophils (a type of white blood cell) in the blood, lungs and tissues. Having too many eosinophils in your blood can damage the airways and can cause your asthma to get worse or can increase the number of your asthma flare ups.

NUCALA is used to treat asthma by reducing the frequency of asthma flare ups in adolescents (over 12 years of age) and adults who are already receiving asthma medicines, but whose asthma flare ups are not well controlled by medicines such as high-dose corticosteroid inhalers or beta-agonist inhalers.

NUCALA can also be used to help reduce the daily dose of oral corticosteroids in patients taking these medicines to control asthma symptoms and flare ups.

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

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

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 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.

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

This medicine is available only with a doctor's prescription.

Before you use NUCALA

Your doctor has weighed any risks of you using NUCALA against the benefits he or she expects it will have for you. You can talk to your doctor about the risks and benefits of using this medicine.

When you must not use it

Do not use NUCALA if:

- you are allergic to mepolizumab or any of the other ingredients of this medicine (listed at the end of this leaflet).

Allergic or allergic-like events often occur within minutes to hours after the medicine is administered, but in some instances symptoms can have a delayed onset of up to several days.

Some of the symptoms of an allergic reaction may include:

- chest tightness, cough, wheezing or difficulty breathing
- drop in blood pressure (fainting, dizziness, feeling lightheaded)
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or redness on the skin
- stomach pain or discomfort
- vomiting.

If you think any of these apply to you, do not use NUCALA until you have checked with your doctor.

If you are pregnant or if you think you may be pregnant do not use NUCALA without asking your doctor.

Your doctor will consider the benefit to you and the risk to you or your baby of using NUCALA while you are pregnant.

If you plan to become pregnant, tell your doctor before starting treatment with NUCALA.

Your doctor will discuss with you the benefits and potential risks of being given this medicine during pregnancy.

If you are breast-feeding, check with your doctor before you take NUCALA.

It is not known whether the ingredients of NUCALA can pass into breast milk. Your doctor can discuss with you the risks and benefits involved.

For severe eosinophilic asthma, NUCALA is not recommended for children aged under 12 years or in adolescents who weigh less than 45 kg, as the safety and effectiveness are not known in this population.

For EGPA, NUCALA may be used in adults only. NUCALA has not been tested in children with EGPA.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Your doctor should give you a Personal Action Plan to help manage your asthma. This plan will include what medicines to take regularly to control your asthma, as well as what "reliever" medicines to use when you have sudden attacks of breathlessness or wheezing.

Ask your doctor or pharmacist if you have any questions about your Action Plan.

Talk to your doctor before you use NUCALA if:

- you have had an allergic reaction before
- you have an existing infection or live in a region where infections caused by parasites are common or if you are travelling to such a region as NUCALA may weaken your resistance to such infections. Parasitic infections should be treated prior to starting treatment with NUCALA.

You may need extra check-ups while you are being treated with NUCALA.

NUCALA does not treat acute asthma symptoms, such as a sudden asthma flare up. Therefore, NUCALA should not be used to treat such symptoms.

Asthma-related side effects or flare ups may occur during treatment with NUCALA.

If your asthma symptoms get worse while receiving injections of NUCALA speak to your doctor.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. This should include all of the medicines that you are using for your asthma.

Do not suddenly stop taking your corticosteroids once you have started NUCALA.

Corticosteroids must be stopped gradually, under the supervision of your doctor.

How to use NUCALA

NUCALA is given by injection under your skin (subcutaneous injection).

NUCALA is a 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.

Your doctor or nurse will decide if you or your caregiver can inject NUCALA. If they consider self-administration appropriate, your doctor or nurse will provide training to show you or your caregiver the correct way to use NUCALA.

You can inject NUCALA under your skin in either your stomach area (abdomen) or upper leg (thigh). Your caregiver can inject NUCALA at these sites or into your upper arm. You

should not give injections into areas where the skin is tender, bruised, red, or hard.

How much to use

Severe eosinophilic asthma:

Adults and adolescents 12 years and over:

The recommended dose is 100 mg. You will have 1 injection, once every four weeks.

EGPA:

Adults aged 18 years and over:

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

If you miss a dose

If your doctor or healthcare professional usually gives you your injection of NUCALA:

If a dose of NUCALA is missed contact your doctor or hospital as soon as possible to re-schedule your appointment.

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 or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

In Australia, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much NUCALA. Do this even if there are no signs of discomfort or poisoning.

While you are using NUCALA

Things you must do

If you have an Action Plan for your asthma that you have agreed with your doctor, follow it closely at all times.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not stop injections of NUCALA unless your doctor tells you to. Interrupting or stopping the treatment with NUCALA may cause your asthma symptoms and flare ups to come back or occur more frequently.

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.

Things to be careful of

This medicine is not expected to affect your ability to drive a car or operate machinery. However, it is prudent to be careful with driving or operating machinery until you know how NUCALA affects you.

Side effects

Like all medicines, NUCALA 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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Very common side effects

This may affect more than 1 in 10 people:

- headache

Common side effects

These may affect up to 1 in 10 people:

- injection-site reaction (pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given)
- eczema (itchy red patches on the skin)
- back pain
- pharyngitis (sore throat)
- lower respiratory tract infection (congestion, cough, discomfort)
- nasal congestion (stuffy nose)
- upper abdominal pain (stomach pain or discomfort in the upper area of the stomach)
- urinary tract infection (blood in urine, painful and frequent urination, fever, pain in lower back)

- fever (high temperature).
- Some side effects may occur more frequently in people with EGPA, including headache, injection site reactions, diarrhoea and vomiting.

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

If you think you are having an allergic reaction to NUCALA, stop using this medicine and tell your doctor or a nurse immediately or go to the Emergency Department at your nearest hospital.

Symptoms of an allergic reaction usually include some or all of the following:

- chest tightness, cough, wheezing or difficulty breathing
- drop in blood pressure (fainting, dizziness, feeling lightheaded)
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives, or redness on the skin
- stomach pain or discomfort
- vomiting

If you get any side effects, talk to your doctor, pharmacist or nurse.

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

Storage

Do not use NUCALA after the expiry date shown on the pack. The expiry date refers to the last day of that month.

Store at 2°C to 8°C (Refrigerate. Do not freeze).

The pre-filled pen or pre-filled syringe can be removed from the refrigerator and kept in its unopened pack for up to 7 days at room temperature (up to 30°C), when protected from light.

The pre-filled pen or pre-filled syringe must be administered within 8 hours once the pack is opened. Discard the medicine if it has not been administered within 8 hours.

Do not store NUCALA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep it where children cannot reach it.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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 pre-filled pen/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 pre-filled syringe.

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

Ingredients

The active ingredient in NUCALA is mepolizumab.

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

The other ingredients are:

- sucrose
- dibasic sodium phosphate heptahydrate

- polysorbate 80
- citric acid monohydrate
- disodium edetate
- water for injections

Supplier

NUCALA is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford Victoria 3067

Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups.

This leaflet was prepared on 18 November 2019.

The information provided applies only to: NUCALA Solution for injection in pre-filled pen (auto-injector) and pre-filled syringe (safety syringe).

Solution for injection in pre-filled pen: AUST R 317304

Solution for injection in pre-filled syringe: AUST R 312652

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Version 1.0

INSTRUCTIONS FOR USE

NUCALA (mepolizumab) solution for injection in pre-filled pen (auto-injector)

Administer once every 4 weeks.

Please read and 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 from your doctor or healthcare professional.

NUCALA pre-filled pen is for use under the skin only (subcutaneous).

If you have any questions about your medicine, please speak to your doctor or healthcare professional.

How to store NUCALA

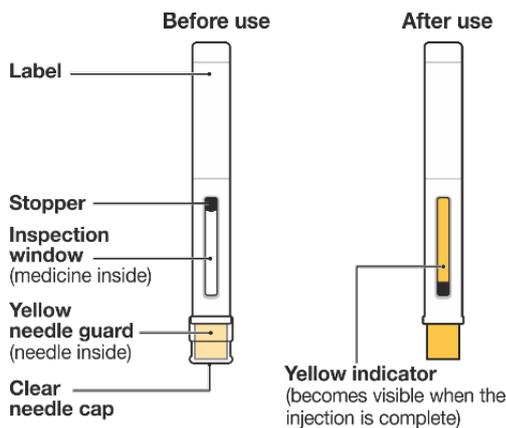
- Keep refrigerated (2-8°C) before use
- Do not freeze
- Keep in the carton to protect from light
- Keep out of the sight and reach of children
- If necessary, the pre-filled pen may be kept at room temperature, up to 30°C, for no more than 7 days, when stored in the original carton
 - Do not store it 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 you are ready to use NUCALA.**

Know your pre-filled pen



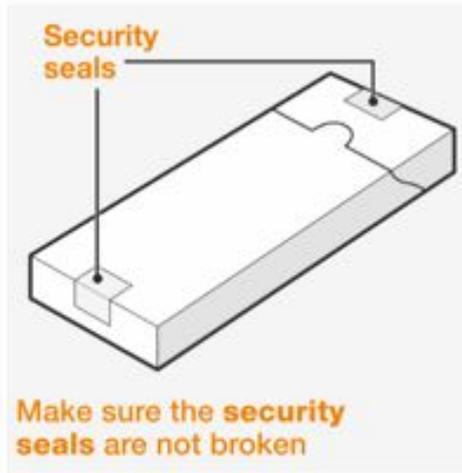
Prepare

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.

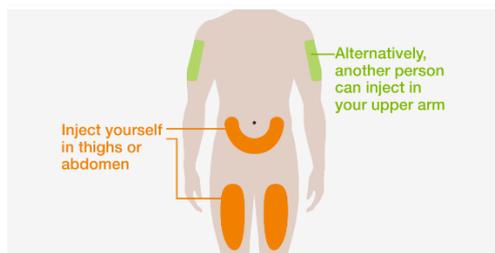
Do not warm the pen in a microwave, hot water, or direct sunlight.

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



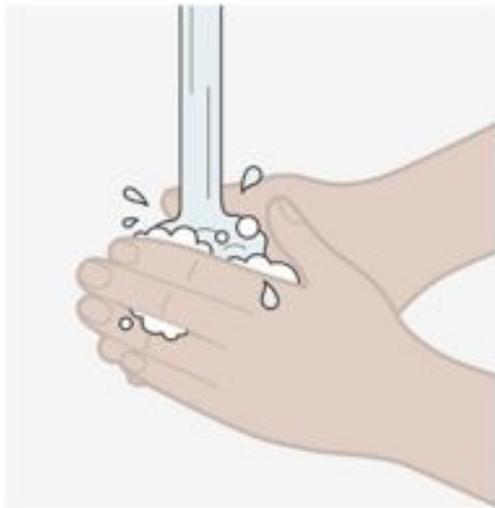
- You can inject NUCALA into your thigh or abdomen.
- If someone else gives you the injection, they can also use your upper arm.

- If your doctor has prescribed 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

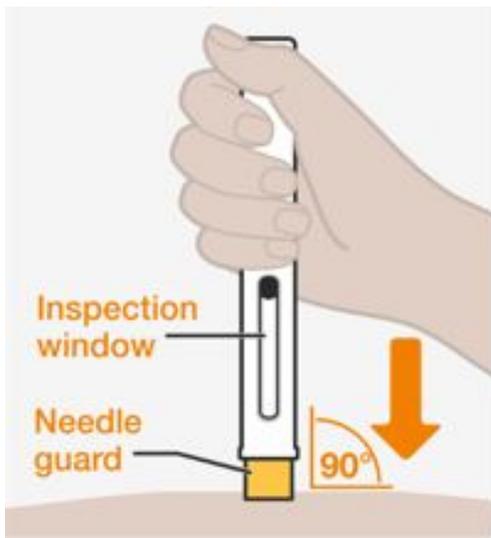


- Remove the clear needle cap from the pen by firmly pulling it straight off.
- Do not worry if you see a drop of liquid at the end of the needle. This is normal.
- Inject straight after removing the needle cap, and always within 5 minutes.

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

FOR MORE INFORMATION

Read the Consumer Medicine Information before use:

Consumer Medicine Information is available online at www.gsk.com.au/nucala

For more information on NUCALA, please see your doctor or pharmacist.

Distributed in Australia by:

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Abbotsford Victoria 3067

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September 2019

Version 1.0

INSTRUCTIONS FOR USE

NUCALA (mepolizumab) solution for injection in pre-filled syringe (safety syringe)

Administer once every 4 weeks.

Please read and 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 from your doctor or healthcare professional.

NUCALA pre-filled syringe is for use under the skin only (subcutaneous).

If you have any questions about your medicine, please speak to your doctor or healthcare professional.

How to store NUCALA

- Keep refrigerated (2-8°C) 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

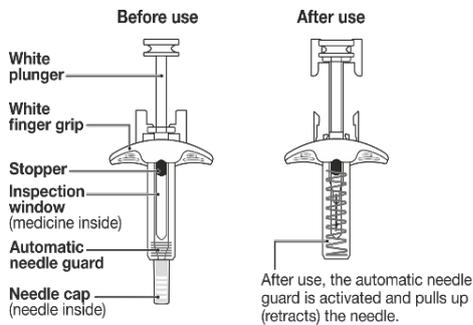
Before you use NUCALA

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 you are ready to use NUCALA.**

Know your pre-filled syringe



Prepare

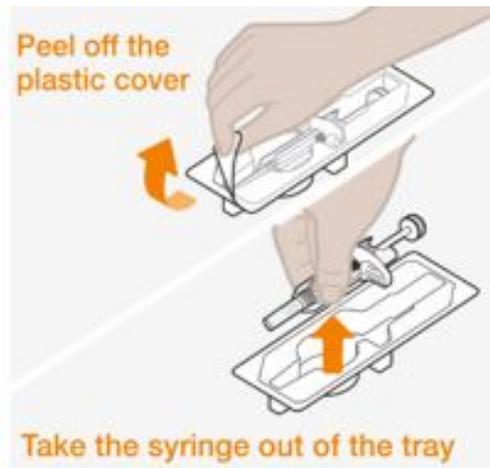
1. Get ready what you need

- 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



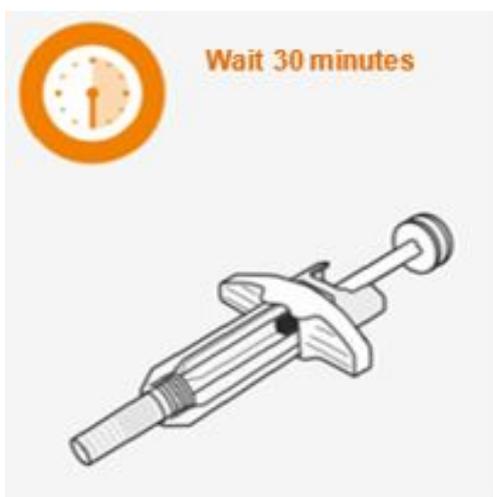
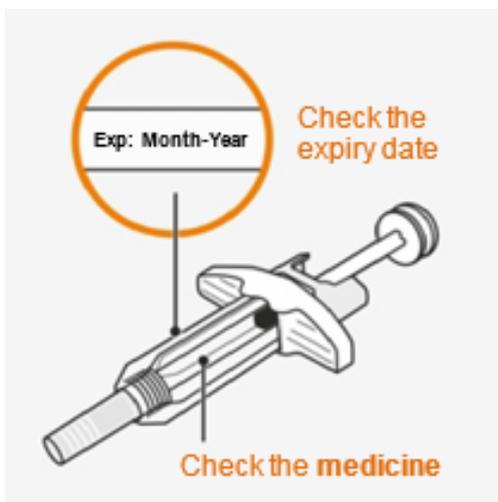


- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel back the film cover from the tray.
- Holding the middle of the syringe, carefully take it out of the tray.
- Place the syringe on a clean, flat surface, at room temperature, away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

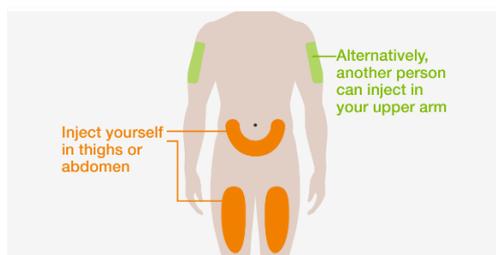
Do not warm the syringe in a microwave, hot water, or direct sunlight.

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

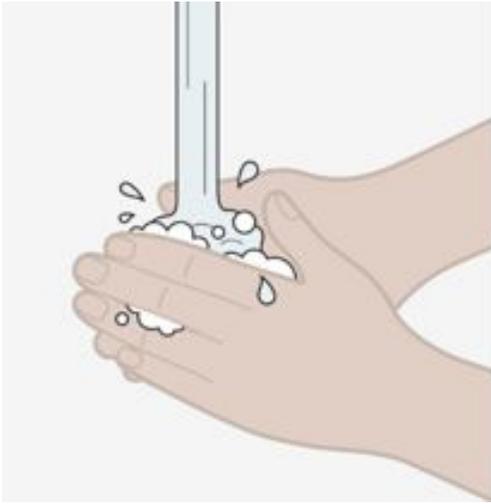


- You can inject NUCALA into your thigh or abdomen.
- If someone else gives you the injection, they can also use your upper arm.
- If your doctor has prescribed more than one injection to complete your dose then leave at least 5 cm between each injection site.

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

FOR MORE INFORMATION

Read the Consumer Medicine Information before use:

Consumer Medicine Information is available online at www.gsk.com.au/nucala

For more information on NUCALA, please see your doctor or pharmacist.

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