YOUR GUIDE TO NUCALA FOR HYPEREOSINOPHILIC SYNDROME (HES)

NUCALA®
mepolizumab

GSK

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Welcome to NUCALA

This guide has been written for people like you, those with hypereosinophilic syndrome (HES) who have also been prescribed NUCALA.

NUCALA has been prescribed by your doctor to help reduce the number of eosinophils in the blood and help reduce your symptoms and prevent flares.

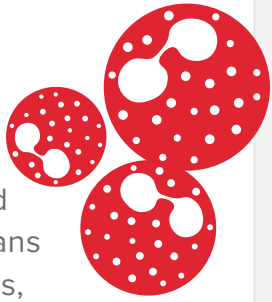
Inside, you'll find useful information on HES and NUCALA. You'll also find answers to questions you may have before and during your treatment.

What is hypereosinophilic syndrome?

Hypereosinophilic Syndrome

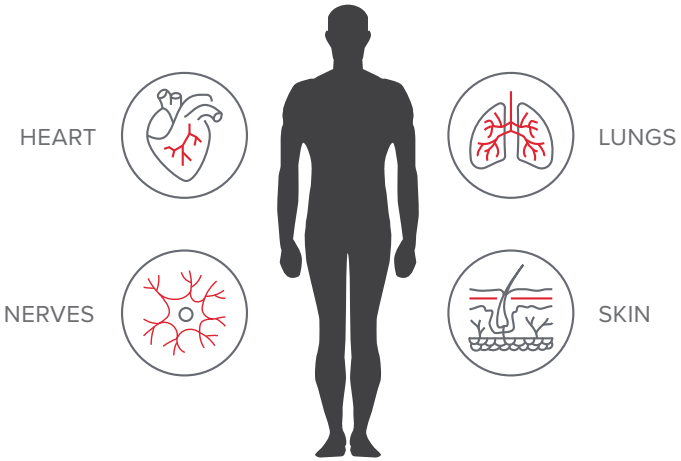
Hypereosinophilic (*hy-per-ee-o-sin-o-phil-ik*) syndrome (HES) is a condition in which there are a high number of eosinophils (a type of white blood cell) in the blood. These cells can damage organs in the body, particularly the heart, lungs, nerves, and skin. The most common symptoms during a HES flare include abdominal pain or bloating, breathlessness, chills or sweats, muscle or joint pain and sinonasal symptoms (pertaining to the nose and nasal sinuses).

Eosinophils



Eosinophils are a type of white blood cell that are present in high numbers in the blood in HES. They are associated with damage that can be done to organs in the body, particularly the heart, lungs, nerves, and skin. In adults, NUCALA reduces the number of eosinophils in the blood and helps reduce symptoms and prevents flares.

Organs that can be damaged by HES



The most common symptoms during a HES flare include:

What is NUCALA?

NUCALA is a medication used to treat adults who have HES — a condition in which people have too many eosinophils (a type of white blood cells) in the blood.

Your doctor may assess the following before prescribing NUCALA:

The kinds of medications you were taking

The results from your blood test (the level of eosinophils found in your blood)

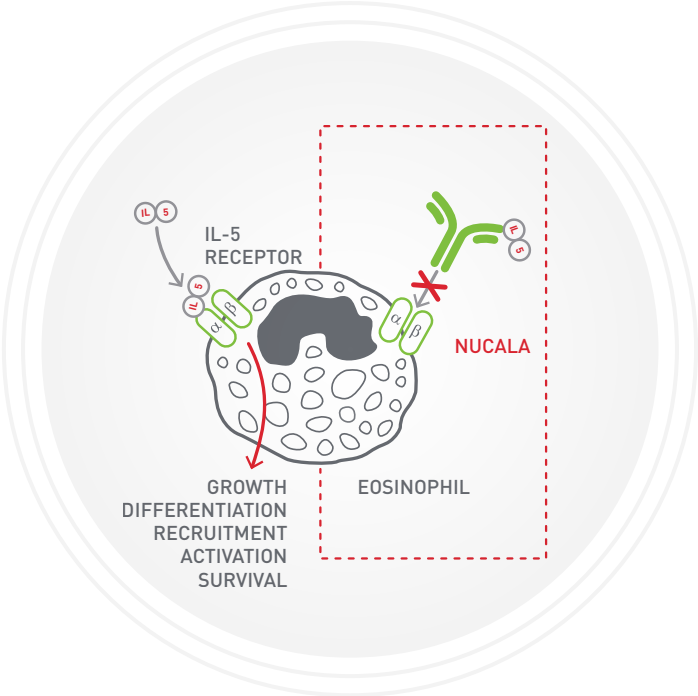
Your symptoms such as abdominal pain or bloating, breathlessness, chills or sweats, muscle or joint pain and sinonasal symptoms.

How does NUCALA work?

NUCALA contains the medicine mepolizumab (*meh-poh-liz-ooh-mab*), which works by blocking a protein called interleukin-5 (IL-5).

By blocking the action of IL-5, NUCALA:

- Limits the production of more eosinophils in the bone marrow
- Lowers the number of eosinophils in the blood, lungs, and tissues



How is NUCALA taken?

NUCALA is given as 3 injections, under the skin (subcutaneous), once every 4 weeks.

Do not stop treatment with NUCALA unless advised by your doctor.

Interrupting or stopping the treatment with NUCALA may cause your symptoms to become worse or occur more frequently. If your symptoms get worse when being treated with NUCALA, immediately tell your doctor.

Consult your healthcare professional if you have questions about your medication.

Tell your doctor if you are taking corticosteroids or other medicines for the treatment of HES. **Do not suddenly stop taking** your corticosteroids or other medicines once you have started NUCALA. Corticosteroids must be stopped gradually, under the direction and supervision of your doctor.

Tell your healthcare professional about all the medicines you take or have recently taken, including drugs, or medicines obtained without a prescription (vitamins, minerals, natural supplements, or alternative medicines).

What is the recommended dose of NUCALA?

Adults (≥18 years of age)	300 mg, given as 3 injections under the skin (subcutaneous) every 4 weeks

NUCALA in a pre-filled autoinjector or safety syringe can be given by a healthcare professional, a patient, or a caregiver. A healthcare professional will decide if you or your caregiver can inject NUCALA. If appropriate, training will be provided to show the correct way to administer the injections before you use NUCALA at home.

What do in-clinic injections involve?

You might have already had your first NUCALA injection, but if you haven't, you probably want to know what to expect.

- The injection is given by a healthcare professional.
- The injection goes just **underneath the skin** (subcutaneously).
- NUCALA injections are given once every 4 weeks.

Planning for your appointments

You might wonder how to remember your injection appointments. After all, it may be easy to forget doing something new like taking your medicine once every 4 weeks...but it's important to take NUCALA as prescribed by your doctor. Here are **a few tips to help you remember** planning for your NUCALA injections:

- Use your smartphone to set up automated reminders or write a reminder on your calendar.
- Choose the same day of the week and work it into your existing routine.
- Work with your PSP nurse to set up reminder calls.
- Use your injection tracker at the back of this guide to help you stay on top of your appointments.

Use your NUCALA injection tracker to help you stay on top of your appointments.

What if I want to receive NUCALA by self-injecting at home?

NUCALA in a pre-filled autoinjector or a safety syringe can be given at home by you or your caregiver.

Your healthcare professional will decide if you or your caregiver can inject NUCALA.

If appropriate, training will be provided to show the correct way to administer the injections before you use NUCALA unsupervised at home.

For more information on self-injection at home

Please follow the instructions provided in the carton with your medicine. Detailed instructions on preparing your NUCALA and your injection site, as well as instructions for self-injecting, are available at NUCALA.ca.

You can also **scan the QR code** with your smartphone to access the website.

If you have any other questions, please ask your healthcare professional.

How do I use my pre-filled autoinjector or safety syringe?

NUCALA is available in a pre-filled autoinjector or safety syringe. It can be given by a healthcare professional, a patient, or a caregiver. Your healthcare professional will decide if you or your caregiver can inject NUCALA. If appropriate, training will be provided to show the correct way to administer the injections before you use NUCALA unsupervised at home.

Please refer to the instructions on how to use your pre-filled autoinjector or safety syringe at the end of this brochure.

What if I miss a dose?

If you realize you've missed a dose, **you or your caregiver should inject the next dose of NUCALA as soon as you remember.** Then, you can resume dosing on the usual day of administration.

If 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 healthcare professional.

How can I travel with my NUCALA?

Travelling with NUCALA may be possible. Speak to your healthcare professional before doing so. **Remember that you need to keep it in the original packaging and protected from light.** You may keep NUCALA at room temperature, below 30°C, for no more than 7 days when kept in the original carton.

If you do take your medicine out of its carton, it should be used within 8 hours. Throw the NUCALA away if it has been kept out of the refrigerator for more than 7 days when stored in the original carton. Throw the NUCALA away if the carton is opened and not used within 8 hours.

What side effects can NUCALA cause?

As with all medications, patients may experience side effects while on NUCALA. The side effects caused by NUCALA are usually mild or moderate, but can occasionally be serious.

Allergic or allergic-like reactions

These are different from injection-site reactions. They are allergic or allergic-like reactions that may be severe. They generally happen very quickly (within minutes or hours) after the medicine has been taken, but in some cases, they can happen up to several days later. You may experience this type of reaction even if it is not your first injection.

Symptoms of allergic reactions can include:

- Becoming very wheezy, cough, difficulty breathing, chest tightness
- Fainting, feeling dizzy, suddenly feeling weak or light-headed (due to a drop in blood pressure)
- Swelling of the eyelids, face, lips, tongue, mouth, and other areas of the body (angioedema), skin rash, hives, redness

Stop taking NUCALA and seek medical attention immediately if you think you may be having a reaction.
If you think you have had a reaction like this before, **tell your doctor before you start taking NUCALA.**

Very common side effects

Very common side effects (which may affect **more than 1 in 10** people) include:

- Headache
- Joint pain
- Sinus infection
- Cough, sore throat, runny nose, nasal congestion (upper respiratory tract infection)
- Diarrhea
- Vomiting
- Back pain
- Rash
- Neck pain
- Mouth and/or throat pain
- Injection site reactions (including pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given)

Common side effects

Common side effects (which may affect **up to 1 in 10** people) include:

- Sore throat (pharyngitis)
- Congestion, cough, discomfort, fever (lower respiratory tract infection)
- Stuffy nose (nasal congestion)
- Stomach pain or discomfort in the upper area of the stomach (upper abdominal pain)
- Itchy red patches on the skin (eczema)
- Urinary tract infection (blood in urination, painful and frequent urination, fever, pain in lower back)
- High temperature (fever)
- Muscle and/or bone pain
- Sensation of spinning or feeling off balance, dizziness (vertigo)
- Lack of energy, muscle weakness
- Sensation of tingling and/or numbness (paraesthesia)
- Blurry vision

These are not all the possible side effects that you may feel when taking NUCALA. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them

Stop taking the drug and get immediate medical help if you experience sudden, severe allergic reactions such as:

- Skin rash (hives) or redness
- Swelling, sometimes of the face or mouth (angioedema)
- Becoming very wheezy, coughing, or having difficulty breathing
- Suddenly feeling weak or light-headed (may lead to collapse or loss of consciousness)

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional right away.

For more information on side effects, please see the patient information leaflet that comes with your medicine, or contact your clinic for advice.

If you get any side effects, tell your doctor or nurse immediately. This includes any possible side effects not listed here.

USING YOUR AUTOINJECTOR

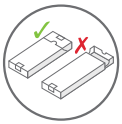
Administration

Instructions for use of your autoinjector

Let's go over the proper way to store your autoinjector

Keep it refrigerated (2°C to 8°C) before use.

- **Do not** store it above 30°C.
- **Do not** freeze.

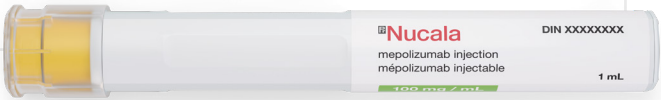


Keep it in the carton to protect from light.

If needed, you can keep the unopened carton out of the refrigerator, at below 30°C, for no more than 7 days, when stored in the original carton. **Discard if the unopened carton is left out of the refrigerator for more than 7 days.**

Use within 8 hours once the carton is open. Discard if not used within 8 hours.

Do not shake.



Things to remember

Do not use if the expiry date has passed.

Do not remove the needle cap until just before your injection.

Do not use the autoinjector more than once. Throw away the autoinjector in a sharps disposal container after your injection and dispose of appropriately as per local requirements.

Do not use the autoinjector if it was dropped onto a hard surface or looks damaged.

Do not share the autoinjector with other people.

Keep NUCALA out of the reach of children.

Gather supplies

Before you start, find a comfortable, well-lit, and clean surface. Make sure you have the following ready:

NUCALA autoinjector

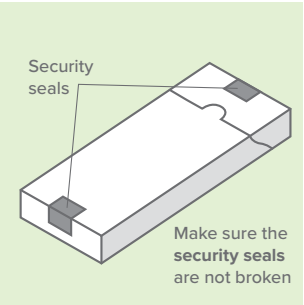
Alcohol wipe (not included)

Cotton ball or gauze (not included)

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

Step one: Prepare

1. Take out your autoinjector

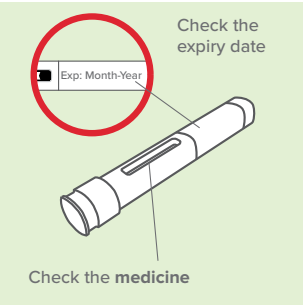


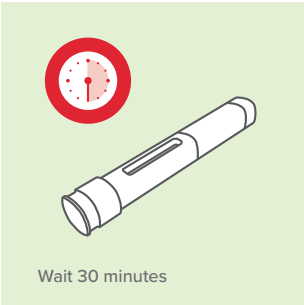
- Take the carton out of the refrigerator. **Check the security seals are not broken.**
- Remove the tray from the carton.
- Peel the film cover from the tray.
- **Holding the middle** of the autoinjector, carefully take it out of the tray.

- Place the autoinjector on a clean, flat surface, at room temperature, away from direct sunlight and out of the reach of children.
- **Do not** use the autoinjector if the security seal on the carton is broken.
- **Do not** remove the clear needle cap at this stage.

Step one: Prepare

2. Inspect and wait 30 minutes before use



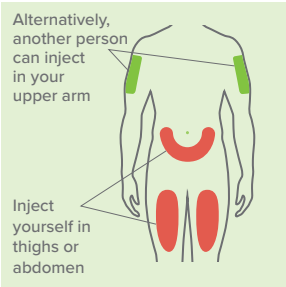


- Check the expiry date on the label of the autoinjector.
- Look in the inspection window to check that the liquid is clear (free from cloudiness or particles) and colourless or pale yellow or pale brown. It is normal to see one or more air bubbles.
- **Wait 30 minutes** (and no more than 8 hours) before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

- **Do not** use if the expiry date has passed.
- **Do not** warm your autoinjector 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 autoinjector if it has been left out of the carton for more than 8 hours.
- **Do not** remove the needle cap during this step.

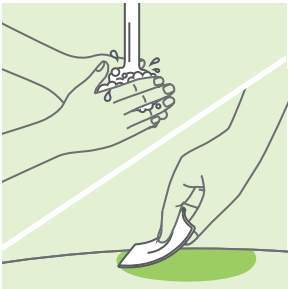
Step one: Prepare

3. 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 (2 inches) between each injection site**.
- **Do not** inject where your skin is bruised, tender, red, or hard.
- **Do not** inject within 5 cm (2 inches) of your navel (belly button).

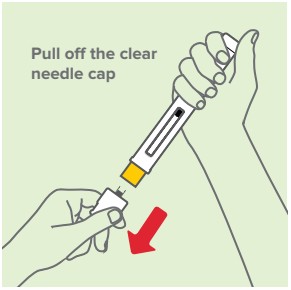
4. Clean your injection site



- Wash your hands with soap and water.
- Clean your injection site by wiping your 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.

Step two: Inject

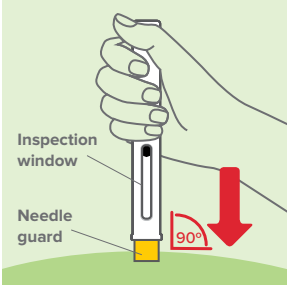
5. Remove the clear needle cap



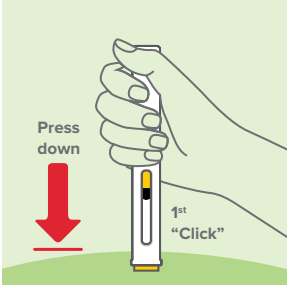
- Remove the clear needle cap from the autoinjector by firmly pulling it **straight off**.
- **Do not** worry if you see a drop of liquid at the end of the needle. This is normal.
- **Inject right after** removing the needle cap, and always within 5 minutes.
- **Do not** touch the yellow needle guard with your fingers. This could activate the autoinjector too soon and may cause a needle injury.
- **Do not** put the needle cap back onto the autoinjector, as it may accidentally start the injection.

Step two: Inject

6. Start your injection



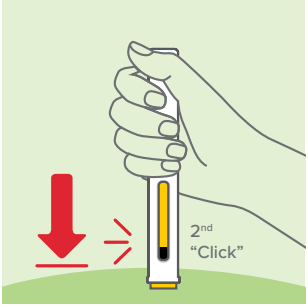
- Hold the autoinjector with its inspection window **facing towards** you, so you can see it, and with the yellow needle guard facing down.
- Place the autoinjector straight onto your injection site with the yellow needle guard **flat against the surface of your skin, as shown.**
- To start your injection, push the autoinjector all the way down and **keep it held down** against your skin. This will make the yellow needle guard slide up into the autoinjector.



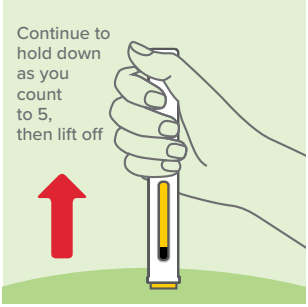
- You should hear the first **"click" to tell you your injection has started**.
- The yellow indicator will move down through the inspection window as you receive your dose.
- **Do not** lift the autoinjector from your skin at this step, as that may mean you don't get your full dose of medicine. **Your injection may take up to 15 seconds to complete**.
- **Do not** use the autoinjector **if the yellow needle guard doesn't slide up** as described. Dispose of it (see Step 8), and start again with a new autoinjector.

Step two: Inject

7. Hold the autoinjector in place to complete your injection



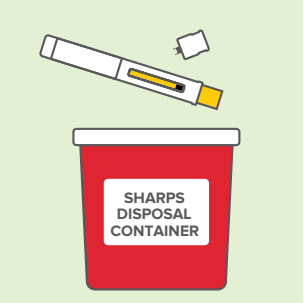
- **Continue to hold the autoinjector down until you hear the second "click",** and the stopper and yellow indicator have stopped moving and fill the inspection window.
- **Continue to hold the autoinjector** in place while you count to 5. Then lift the autoinjector away from your skin.
- **If you do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



- **Do not lift the autoinjector 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 ball or gauze on the area for a few moments if necessary.
- **Do not rub your injection site.**

Step three: Dispose

8. Dispose of the used autoinjector



- Dispose of the used autoinjector and needle cap **according to local requirements**.
- When your sharps disposal container is almost full, you will need to **follow your community guidelines** for the right way to dispose of it.

For information about how to safely dispose of your autoinjectors and needle caps, speak to your healthcare professional or visit **healthsteward.ca**.*

Do not throw away your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

Keep your sharps disposal container out of the reach of children.

*Healthsteward.ca is a third-party website that is not managed or monitored by GSK.

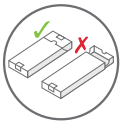
USING YOUR
PRE-FILLED SAFETY SYRINGE

Instructions for use of your pre-filled safety syringe

Let's go over the proper way to store your pre-filled safety syringe

Keep it refrigerated (2°C to 8°C) before use.

- **Do not** store it above 30°C.
- **Do not** freeze.



Keep it in the carton to protect from light.

If needed, you can keep the unopened carton out of the refrigerator, at below 30°C, for no more than 7 days, when stored in the original carton. **Discard if the unopened carton is left out of the refrigerator for more than 7 days.**

Use within 8 hours once the carton is open. Discard if not used within 8 hours.

Do not shake.

Things to remember

Do not use if the expiry date has passed.

Do not remove the needle cap until just before your injection.

Do not use the syringe more than once. Throw away the syringe in a sharps disposal container after your injection and dispose of it appropriately as per local requirements.

Do not use the syringe if it was dropped onto a hard surface or looks damaged.

Do not share the syringe with other people.

Keep NUCALA out of the reach of children.

Gather supplies

Before you start, find a comfortable, well-lit, and clean surface. Make sure you have the following ready:

NUCALA pre-filled safety syringe

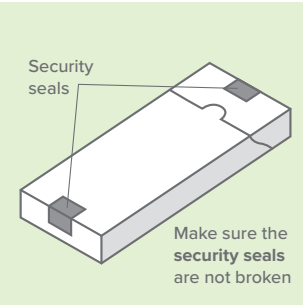
Alcohol wipe (not included)

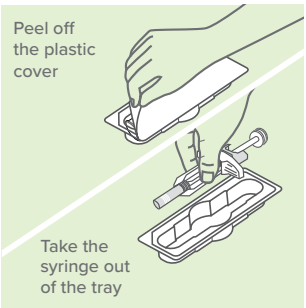
Cotton ball or gauze (not included)

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

Step one: Prepare

1. Take out your pre-filled syringe



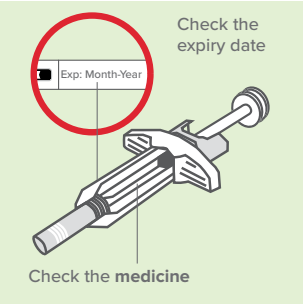


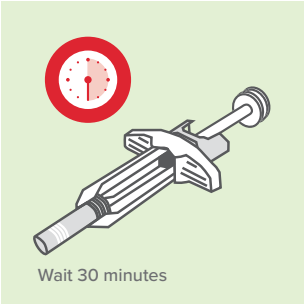
- Take the carton out of the refrigerator. **Check the security seals are not broken**.
- Remove the tray from the carton.
- Peel the film cover from the tray.
- **Holding the middle** of the syringe, carefully take it out of the tray.

- 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.

Step one: Prepare

2. Inspect and wait 30 minutes before use



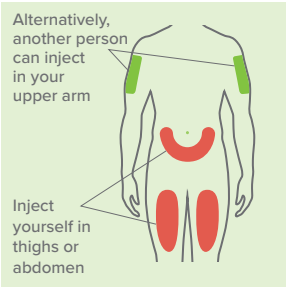


- Check the expiry date on the label of the syringe.
- Look in the inspection window to check that the liquid is clear (free from cloudiness or particles) and colourless or pale yellow or pale brown. It is normal to see one or more air bubbles.
- **Wait 30 minutes** (and no more than 8 hours) before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

- **Do not** use if the expiry date has passed.
- **Do not** warm your 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 it has been left out of the carton for more than 8 hours.
- **Do not** remove the needle cap during this step.

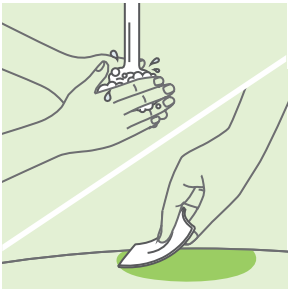
Step one: Prepare

3. 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 (2 inches) between each injection site**.
- **Do not** inject where your skin is bruised, tender, red, or hard.
- **Do not** inject within 5 cm (2 inches) of your navel (belly button).

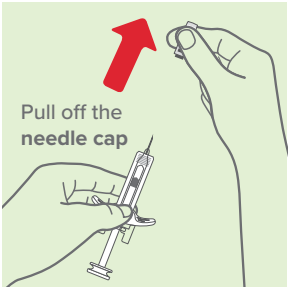
4. Clean your injection site



- Wash your hands with soap and water.
- Clean your injection site by wiping your 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.

Step two: Inject

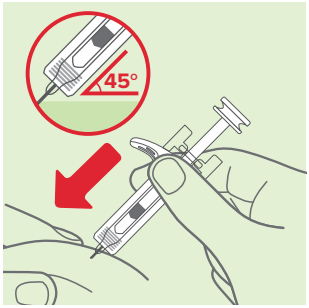
5. Remove the clear needle cap



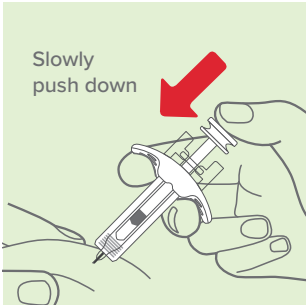
- Remove the needle cap from the syringe by firmly pulling it **straight off**, extending your hand away from the needle end (as shown).
- You may need to pull the needle cap quite firmly to remove it.
- **Inject right after** removing the needle cap, and always within 5 minutes.
- **Do not** worry if you see a drop of liquid at the end of the needle. This is normal.
- **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, as it may cause a needle injury.

Step two: Inject

6. 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.

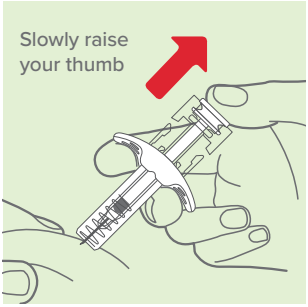


- **Slowly push down** on the plunger to inject your full dose.

Step two: Inject

7. Complete your injection

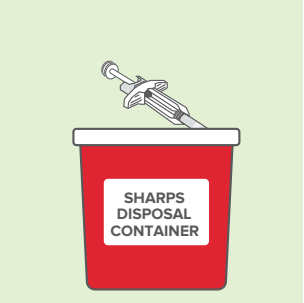
- **Make sure the plunger is pushed all the way down**, until the stopper reaches the bottom of the syringe and all of the solution is injected.



- **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 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.

Step three: Dispose

8. Dispose of the used syringe



- Dispose of the used syringe and needle cap **according to local requirements**.
- When your sharps disposal container is almost full, you will need to **follow your community guidelines** for the right way to dispose of it.

For information about how to safely dispose of your syringes and needle caps, speak to your healthcare professional or visit **healthsteward.ca**.*

Do not throw away your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

Keep your sharps disposal container out of the reach of children.

*Healthsteward.ca is a third-party website that is not managed or monitored by GSK.

The VISTA Patient Support Program:
Here for you along the way

We can help guide you

By enrolling in the VISTA Patient Support Program, you get access to customized services, which may include:

- Reimbursement navigation
- Financial assistance
- Patient education and support
- Pharmacy services

Talk to your doctor for more information.

You can expect a call from your nurse case manager at the **VISTA Patient Support Program** in the next few days. If you do not hear from the program, please contact them via one of the following methods.

The VISTA Patient Support Program

Phone: 1-844-847-4392

Fax: 1-844-410-0653

Email: enrollments@vistafornucala.ca

Please be aware that the caller may appear as Bayshore Healthcare, 1-844-847-4938, or from a nurse with a phone number that you do not recognize.

We're here for you along the way.

Contact GSK Pharmaceutical inquiries for more information at **1-800-387-7374** and do not use the autoinjector if any of the below occur:

- If the security seal on the carton is broken
- If the autoinjector looks damaged
- If the medicine is cloudy or discoloured, or has particles

What now?

We'll say it again because it's an important point.

NUCALA is an ongoing treatment, taken to help reduce symptoms and prevent flares of hypereosinophilic syndrome.

NUCALA is given once every 4 weeks. Always consult your doctor or nurse before changing or stopping any medication, or if you have any questions about your medication.

For more information about your condition and NUCALA, **visit www.nucala.ca or scan the QR code** with your smartphone to access the website.

Notes:

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