

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrNUCALA [*new-ka' la*]

Mepolizumab for Injection

100 mg/mL lyophilized powder for subcutaneous injection

Read this carefully before you start receiving **Nucala** and each time you receive treatment. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Nucala**.

What is Nucala used for?

Severe Eosinophilic Asthma

Nucala (mepolizumab for injection) is a prescription medicine used in addition to other asthma medicines to treat adults, adolescents (12-17 years of age), and children (6-11 years of age) with severe eosinophilic asthma, whose asthma is not controlled with their current asthma medicines, such as high-dose inhalers. Severe eosinophilic asthma is a type of severe asthma in which there is a presence of eosinophils (a type of white blood cell). Eosinophils are associated with inflammation of the airways that can cause your asthma to get worse or can increase the number of asthma attacks. Nucala helps prevent the number of asthma attacks.

Nucala is not used to treat acute asthma symptoms, such as a sudden asthma attack.

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, 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, relieve your nasal congestion and help avoid or delay surgery for nasal polyps.

Eosinophilic Granulomatosis and Polyangiitis (EGPA)

EGPA is a condition where people have inflammation of the blood vessels (vasculitis) due to too many eosinophils (a type of white blood cell) in the blood and tissues. EGPA most commonly affects the lungs and sinuses but often also affects other organs including the skin, heart, kidneys, nerves or bowels. The most common symptoms include extreme fatigue, muscle and joint pain, weight loss, nasal sinus symptoms, and difficulty breathing.

In adults, Nucala, used in addition to corticosteroids, can reduce EGPA symptoms and delay flare-up of these symptoms. Nucala can also help reduce the daily dose of corticosteroids you need to control your symptoms.

Hypereosinophilic Syndrome (HES)

HES is a condition in which there are a high number of eosinophils in the blood. These cells can damage organs in the body, particularly the heart, lungs, nerves, and skin. The most common symptoms of a HES flare include abdominal pain or bloating, difficulty breathing, chills or sweats, muscle or joint pain and nasal sinus symptoms.

In adults, Nucala reduces the number of eosinophils in the blood and helps reduce symptoms and prevents flares.

How does Nucala work?

Nucala contains the active substance, mepolizumab, a monoclonal antibody that works by blocking a specific protein called interleukin-5. By blocking the action of interleukin-5, Nucala limits the production of more eosinophils from the bone marrow and lowers the number of eosinophils in the blood, lungs and tissues.

What are the ingredients in Nucala?

Medicinal ingredients: The active substance is mepolizumab.

Non-medicinal ingredients: The other ingredients are polysorbate 80, sodium phosphate dibasic heptahydrate, and sucrose.

Nucala comes in the following dosage form:

Lyophilized powder for subcutaneous injection; each single-use vial contains 144 mg of mepolizumab (100 mg/mL when reconstituted).

Do not use Nucala if:

- you are **allergic** to mepolizumab or any of the other ingredients of this medicine. **Talk to your doctor** about whether this may apply to you.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use Nucala.

- Medicines of this type (monoclonal antibodies) can cause severe allergic reactions when injected into the body (see **What are the possible side effects from using Nucala?**). If you have had a similar reaction before, tell your doctor before you are given Nucala.
- Nucala does not treat acute asthma symptoms, such as a sudden asthma attack. Therefore, Nucala should not be used to treat such symptoms.
- Tell your doctor if your asthma symptoms remain uncontrolled or get worse while being treated with Nucala.
- Tell your doctor if you are taking corticosteroids or other medicines for the treatment of asthma, Chronic Rhinosinusitis with Nasal Polyps, Eosinophilic Granulomatosis with Polyangiitis, or Hypereosinophilic Syndrome. **Do not suddenly stop taking** your corticosteroids or other medicines once you have started Nucala. Corticosteroids must be stopped gradually, under the supervision of your doctor.

- There are different treatments available for hypereosinophilic syndrome depending on the type of disease, as such, talk to your doctor about genetic testing to guide optimal treatment decision.

Talk about any health conditions or problems you may have, including if you:

- have an existing parasitic infection, live in a region where infections caused by parasites are common, or if you are travelling to such a region. Nucala may weaken your resistance to such infections. Parasitic infections should be treated prior to starting treatment with Nucala.
- have or have not had chickenpox (varicella) or shingles, or if you have or have not received a chickenpox or shingles vaccine.

Pregnancy and breast-feeding:

- If you are pregnant, think you may be pregnant, or are planning to become pregnant, **tell your doctor** before using this medicine. You should not use this medicine if you are pregnant, unless this is considered necessary by your doctor.
- If you become pregnant while being treated with Nucala or within 4 months of stopping treatment with Nucala, tell your doctor immediately.
- It is not known whether the ingredients of Nucala can pass into breast milk. **If you are breastfeeding or plan to breastfeed, you must tell your doctor** before being treated with Nucala.

Other warnings you should know about:

Nucala should not be given to children under 6 years of age for the treatment of severe eosinophilic asthma and should not be given to children and adolescents under 18 years of age for the treatment of CRSwNP, EGPA or HES.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Nucala:

Nucala is given to you as an injection just under the skin (subcutaneously) by a healthcare professional, who is experienced in the monitoring and treatment of signs and symptoms of allergic reactions.

Usual dose:

Severe Eosinophilic Asthma

- **Adults and adolescents (12 years of age and older):** The recommended dose of Nucala for severe eosinophilic asthma in adults and adolescents is 100 mg, given as 1 injection under the skin (subcutaneous) every four weeks.
- **Children (6 to 11 years of age):** The recommended dose of Nucala for severe eosinophilic asthma for children is 40 mg, given as 1 injection under the skin (subcutaneous) every four weeks. This dose is prepared using the Nucala lyophilized powder for subcutaneous injection.

Chronic Rhinosinusitis with Nasal Polyps

The recommended dose of Nucala for CRSwNP in adults is 100 mg, given as 1 injection under the skin (subcutaneous) every four weeks.

Eosinophilic Granulomatosis with Polyangiitis

The recommended dose of Nucala for EGPA in adults is 300 mg, given as 3 injections under the skin (subcutaneous) every four weeks.

Hypereosinophilic Syndrome

The recommended dose of Nucala for HES in adults is 300 mg, given as 3 injections under the skin (subcutaneous) every four weeks.

Do not stop receiving injections of 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.

Overdose:

If you think you, or a person you are caring for, have taken too much Nucala, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of Nucala is missed, contact your healthcare professional, such as doctor or nurse, as soon as possible to re-schedule your appointment.

What are possible side effects from using Nucala?

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

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.

Allergic or Allergic-like reactions

- Some people may have allergic or allergic-like reactions that may be severe (e.g. anaphylaxis). These reactions often occur within minutes to hours after the injection, but sometimes symptoms can start several days later. You may experience this type of reaction even if it is not your first injection of Nucala.

Symptoms can include:

- becoming very wheezy, cough, difficulty breathing, chest tightness
- fainting, dizziness, suddenly feeling weak or lightheaded (due to a drop in blood pressure)
- swelling of your 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 (or your child) may be having a reaction.

If you (or your child) may have had a similar reaction before (see also **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Nucala**), **tell your doctor before you are given Nucala.**

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

- Headache
- Joint Pain
- Sinus Infection
- Cough, sore throat, runny nose, nasal congestion (common cold, chest cold, upper respiratory tract infection)
- Diarrhea
- Vomiting
- Back pain
- Rash
- Neck pain
- Mouth and/or throat pain
- Injection site reaction (pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given)
- Flu (influenza)
- Difficulty breathing (wheezing, cough, shortness of breath)

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

- Nausea
- Constipation
- Bleeding nose (epistaxis)
- Eye or ear infection
- Skin infection (impetigo)
- Pain
- Anger (aggression)
- Dizziness
- Throat redness
- Rash (atopic dermatitis)
- Sore throat (pharyngitis)
- Congestion, cough, discomfort, fever (lower respiratory tract infection)
- Stuffy and/or runny nose, sneezing (nasal congestion, rhinitis)
- 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

Tell your healthcare professional immediately if you get any of these symptoms, or if you notice any side effects not listed in this leaflet.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Sudden, severe allergic reaction (e.g. anaphylaxis): <ul style="list-style-type: none"> • 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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date that is stated on the label.
- The expiry date refers to the last day of the stated month.
- Store in the original carton to protect from light.
- Store below 25°C. Discard unused drug if reconstituted more than 8 hours.
- Do not shake or freeze.

If you want more information about Nucala:

- Talk to your healthcare professional.

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the <https://www.canada.ca/en/health-canada.html> Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.gsk.ca; or, by calling 1-800-387-7374.

This leaflet was prepared by GlaxoSmithKline Inc.

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrNUCALA [*new-ka' la*]

Mepolizumab Injection

100 mg/mL solution for subcutaneous injection (pre-filled autoinjector or pre-filled syringe (safety syringe))

40 mg/0.4 mL solution for subcutaneous injection (pre-filled syringe (safety syringe))

Read this carefully before you start taking **Nucala** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Nucala**.

What is Nucala used for?

Severe Eosinophilic Asthma

Nucala (mepolizumab injection) is a prescription medicine used in addition to other asthma medicines to treat adults and adolescents (12-17 years of age) with severe eosinophilic asthma, whose asthma is not controlled with their current asthma medicines, such as high-dose inhalers. Severe eosinophilic asthma is a type of severe asthma in which there is a presence of eosinophils (a type of white blood cell). Eosinophils are associated with inflammation of the airways that can cause your asthma to get worse or can increase the number of asthma attacks. Nucala helps prevent the number of asthma attacks.

Nucala is not used to treat acute asthma symptoms, such as a sudden asthma attack.

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, 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, relieve your nasal congestion and help avoid or delay surgery for nasal polyps.

Eosinophilic Granulomatosis and Polyangiitis (EGPA)

EGPA is a condition where people have inflammation of the blood vessels (vasculitis) due to too many eosinophils (a type of white blood cell) in the blood and tissues. EGPA most commonly affects the lungs and sinuses but often also affects other organs including the skin, heart, kidneys, nerves or bowels. The most common symptoms include extreme fatigue, muscle and joint pain, weight loss, nasal sinus symptoms, and difficulty breathing.

In adults, Nucala, used in addition to corticosteroids, can reduce EGPA symptoms and delay flare-up of these symptoms. Nucala can also help reduce the daily dose of corticosteroids you need to control your symptoms.

Hypereosinophilic Syndrome (HES)

HES is a condition in which there are a high number of eosinophils 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.

In adults, Nucala reduces the number of eosinophils in the blood and helps reduce symptoms and prevents flares.

How does Nucala work?

Nucala contains the active substance, mepolizumab, a monoclonal antibody that works by blocking a specific protein called interleukin-5. By blocking the action of interleukin-5, Nucala limits the production of more eosinophils from the bone marrow and lowers the number of eosinophils in the blood, lungs and tissues.

What are the ingredients in Nucala?

Medicinal ingredients: The active substance is mepolizumab.

Non-medicinal ingredients: The other ingredients are citric acid monohydrate, EDTA disodium dihydrate, polysorbate 80, sodium phosphate dibasic heptahydrate, and sucrose.

Nucala comes in the following dosage forms:

A solution for subcutaneous injection in pre-filled autoinjector or pre-filled syringe. Each autoinjector contains 100 mg/mL of mepolizumab and pre-filled syringes contain either 100 mg/mL or 40 mg/0.4 mL of mepolizumab.

Do not use Nucala if:

- you are **allergic** to mepolizumab or any of the other ingredients of this medicine. **Talk to your doctor** about whether this may apply to you.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use Nucala.

- Medicines of this type (monoclonal antibodies) can cause severe allergic reactions when injected into the body (see **What are the possible side effects from using Nucala?**). If you have had a similar reaction before, tell your doctor before you are given Nucala.
- Nucala does not treat acute asthma symptoms, such as a sudden asthma attack. Therefore, Nucala should not be used to treat such symptoms.
- Tell your doctor if your asthma symptoms remain uncontrolled or get worse while being treated with Nucala.
- Tell your doctor if you are taking corticosteroids or other medicines for the treatment of asthma, Chronic Rhinosinusitis with Nasal Polyps, Eosinophilic Granulomatosis with Polyangiitis, or Hypereosinophilic Syndrome. **Do not suddenly stop taking** your corticosteroids or other medicines once you have started Nucala. Corticosteroids must be stopped gradually, under the supervision of your doctor.

- There are different treatments available for hypereosinophilic syndrome depending on the type of disease, as such, talk to your doctor about genetic testing to guide optimal treatment decision.

Talk about any health conditions or problems you may have, including if you:

- have an existing parasitic infection, live in a region where infections caused by parasites are common, or if you are travelling to such a region. Nucala may weaken your resistance to such infections. Parasitic infections should be treated prior to starting treatment with Nucala.
- have or have not had chickenpox (varicella) or shingles, or if you have or have not received a chickenpox or shingles vaccine.

Pregnancy and breast-feeding:

- If you are pregnant, think you may be pregnant, or are planning to become pregnant, **tell your doctor** before using this medicine. You should not use this medicine if you are pregnant, unless this is considered necessary by your doctor.
- If you become pregnant while being treated with Nucala or within 4 months of stopping treatment with Nucala, tell your doctor immediately.
- It is not known whether the ingredients of Nucala can pass into breast milk. **If you are breastfeeding or plan to breastfeed, you must tell your doctor** before being treated with Nucala.

Other warnings you should know about:

Nucala should not be given to children under 6 years of age for the treatment of severe eosinophilic asthma and should not be given to children and adolescents under 18 years of age for the treatment of CRSwNP, EGPA or HES. The pre-filled autoinjector or pre-filled syringe should not be used in children.

Tell your healthcare professional about all the medicines you take or have recently taken, including drugs, natural supplements or alternative medicines.

How to take Nucala:

100 mg/mL pre-filled auto-injector or pre-filled syringe (safety syringe)

Nucala is a solution for injection in a single-dose pre-filled autoinjector or a single-dose pre-filled syringe, which can be given by a healthcare professional, you, or your caregiver. Your healthcare professional will decide if you or your caregiver can inject Nucala. If appropriate, they will provide training to show you or your caregiver the correct way to give the injections before you use Nucala. Read the Instructions for Use (IFU) that comes with Nucala 100 mg/mL autoinjector or pre-filled syringe for instructions about the correct way to give yourself an injection.

- Nucala is given by injection under the skin (subcutaneously).
- 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.

40 mg/0.4 mL pre-filled syringe (safety syringe)

Nucala is a solution for injection in a single-dose pre-filled syringe, which must be given by a healthcare professional or a caregiver. Your healthcare professional will decide if you can inject Nucala to the child you are caring for. If appropriate, they will provide training to show you the correct way to use Nucala. Read the Instructions for Use (IFU) that comes with Nucala 40 mg/0.4 mL pre-filled syringe for instructions about the correct way to give a child an injection.

- Nucala is given by injection under the skin (subcutaneously).
- You can inject Nucala under the child's skin in the stomach area (abdomen), upper leg (thigh), or upper arm. You should not give injections into areas where the skin is tender, bruised, red, or hard.

Usual dose:

Severe Eosinophilic Asthma

- **Adults and adolescents (12 years of age and older):** The recommended dose of Nucala for severe eosinophilic asthma in adults and adolescents is 100 mg, given as 1 injection under the skin (subcutaneous) every four weeks.
- **Children (6 to 11 years of age):** Only the lyophilized powder for subcutaneous injection and the 40 mg/0.4 mL pre-filled syringe can provide the correct dose for children. The 100 mg/mL pre-filled autoinjector or pre-filled syringe should not be used in children. The recommended dose of Nucala for severe eosinophilic asthma in children is 40 mg, given as 1 injection under the skin (subcutaneous) every four weeks.

Chronic Rhinosinusitis with Nasal Polyps

The recommended dose of Nucala for CRSwNP in adults is 100 mg, given as 1 injection under the skin (subcutaneous) every four weeks.

Eosinophilic Granulomatosis with Polyangiitis

The recommended dose of Nucala for EGPA in adults is 300 mg, given as 3 injections under the skin (subcutaneous) every four weeks.

Hypereosinophilic Syndrome

The recommended dose of Nucala for HES in adults is 300 mg, given as 3 injections under the skin (subcutaneous) every four weeks.

Do not stop using 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.

Overdose:

If you think you, or a person you are caring for, have taken too much Nucala, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you or your caregiver forget to give an injection of Nucala:

You should inject the next dose of Nucala as soon as you remember. Then, you can resume dosing on the usual day of administration. 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 healthcare professional, such as doctor, pharmacist or nurse.

What are possible side effects from using Nucala?

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

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.

Allergic or Allergic-like reactions:

- Some people may have allergic or allergic-like reactions that may be severe (e.g. anaphylaxis). These reactions often occur within minutes to hours after the injection, but sometimes symptoms can start several days later. You may experience this type of reaction even if it is not your first injection of Nucala.

Symptoms can include:

- becoming very wheezy, cough, difficulty breathing, chest tightness
- fainting, dizziness, suddenly feeling weak or lightheaded (due to a drop in blood pressure)
- swelling of your 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 (or your child) may be having a reaction.

If you (or your child) may have had a similar reaction before (see also **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Nucala**), **tell your doctor before you are given Nucala.**

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

- 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 reaction (pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given)

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

- 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

Tell your healthcare professional immediately if you get any of these symptoms, or if you notice any side effects not listed in this leaflet.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Sudden, severe allergic reaction (e.g. anaphylaxis): <ul style="list-style-type: none"> • 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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date that is stated on the label. The expiry date refers to the last day of the stated month.
- Store in the original carton to protect from light.
- Store refrigerated (2°C to 8°C).
- If necessary, can be removed from the refrigerator and kept in the unopened carton for up to 7 days at below 30°C. **Discard if the unopened carton is left out of the refrigerator for more than 7 days.**
- The pre-filled autoinjector or pre-filled syringe must be administered within 8 hours once the carton is opened. Discard if not administered within 8 hours.
- Do not shake or freeze.

If you want more information about Nucala:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the <https://www.canada.ca/en/health-canada.html> Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.gsk.ca; or, by calling 1-800-387-7374.

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NUCALA (mepolizumab injection)

INSTRUCTIONS FOR USE - PRE-FILLED AUTOINJECTOR

Administer once every four weeks

These INSTRUCTIONS FOR USE should be read together with the rest of the PATIENT MEDICATION INFORMATION in your Nucala package. Contact your healthcare professional if you have any questions about Nucala.

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

How to store Nucala

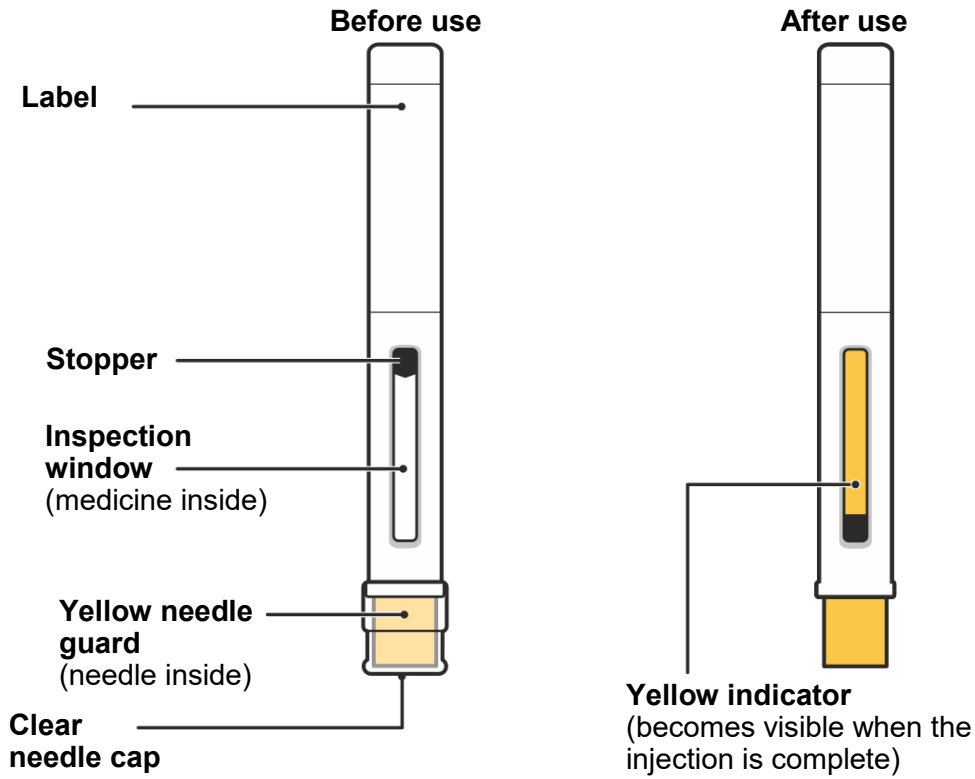
- Keep refrigerated before use.
- Do not freeze.
- Keep in the carton to protect from light.
- Keep out of the sight and reach of children.
- If necessary, the pre-filled autoinjector may be kept at below 30°C, for no more than 7 days, when stored in the original carton. Throw it away if it has not been used within 7 days.
- The autoinjector must be used within 8 hours once the carton is opened. Discard if not used within 8 hours.
- Do not store it above 30°C.

Before you use Nucala

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

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

Figure A. Nucala autoinjector parts

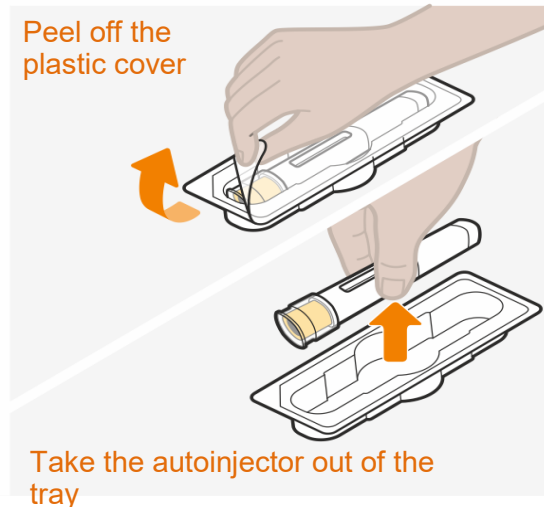
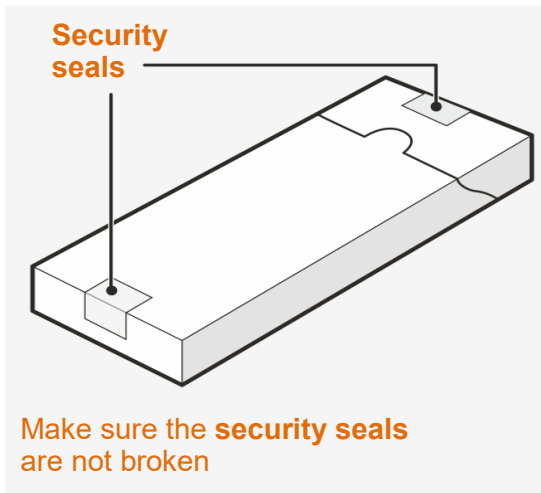


Gather Supplies

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

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

1. Prepare the Nucala autoinjector

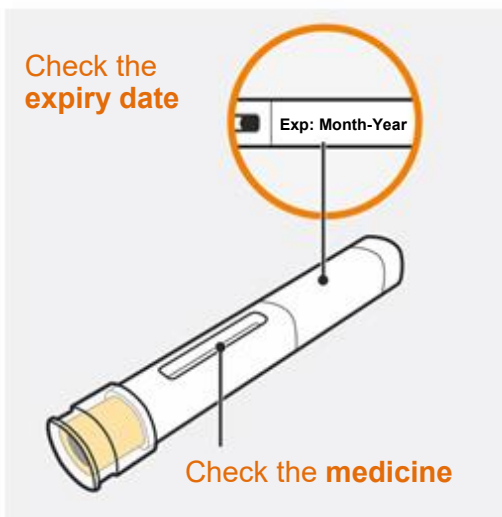


- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel back the film cover from the tray.
- Holding the middle of the autoinjector, carefully take it out of the tray.
- Place the autoinjector on a clean, flat surface, at room temperature,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

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 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.

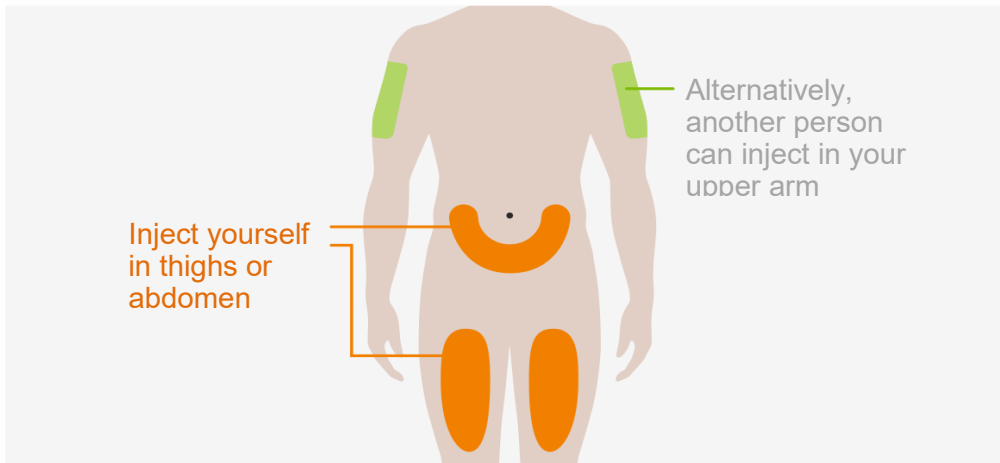
Do not warm the autoinjector in a microwave, hot water, or direct sunlight.

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

Do not use the autoinjector if left out of the carton for more than 8 hours.

Do not remove the needle cap during this step.

3. Choose your injection site

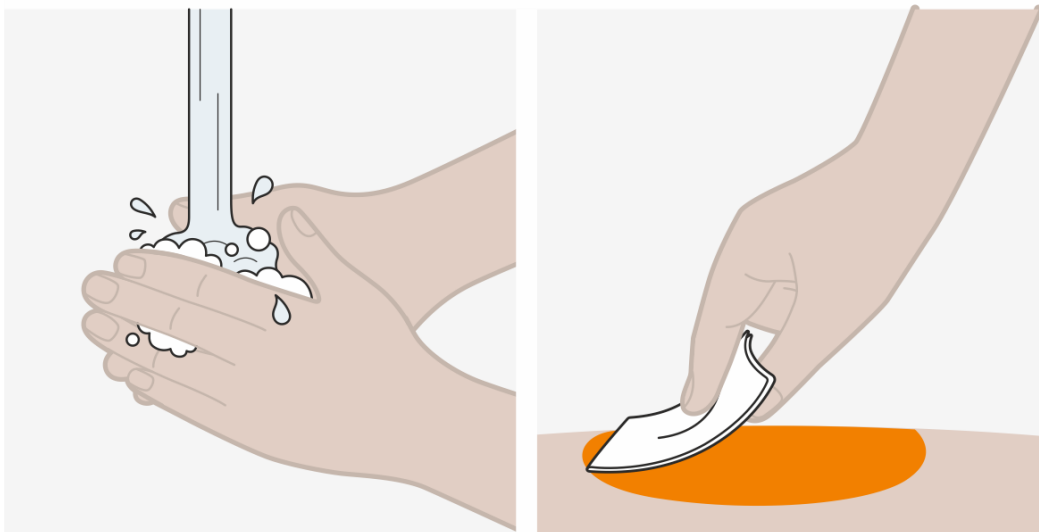


- You can inject Nucala into your thighs or abdomen.
- If someone else gives you the injection, they can also use your upper arm.
- If you need more than one injection to complete your dose then leave at least 5 cm (2 inches) between each injection site.

Do not inject where your skin is bruised, tender, red or hard.

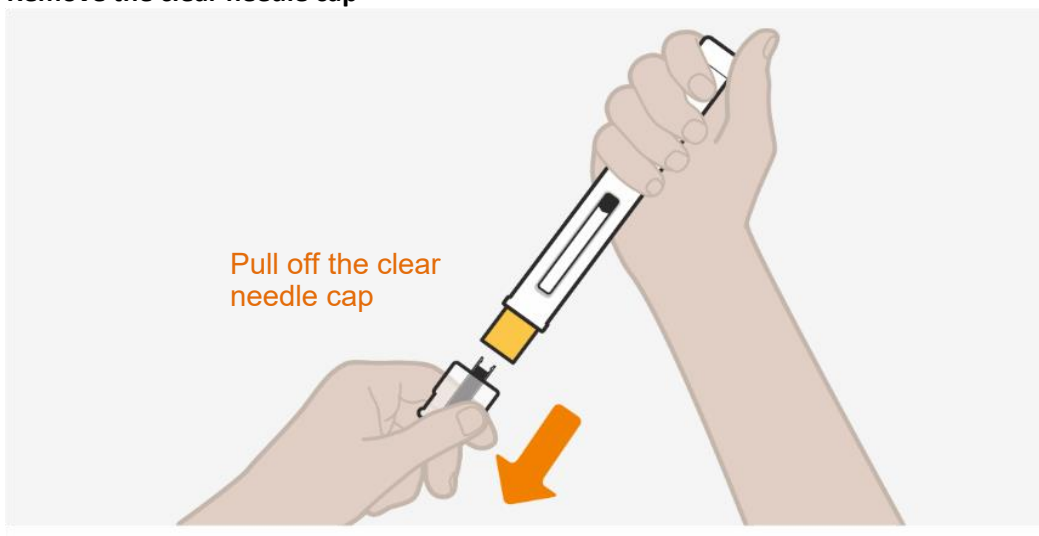
Do not inject within 5 cm (2 inches) of your navel (belly button).

4. Clean your injection site



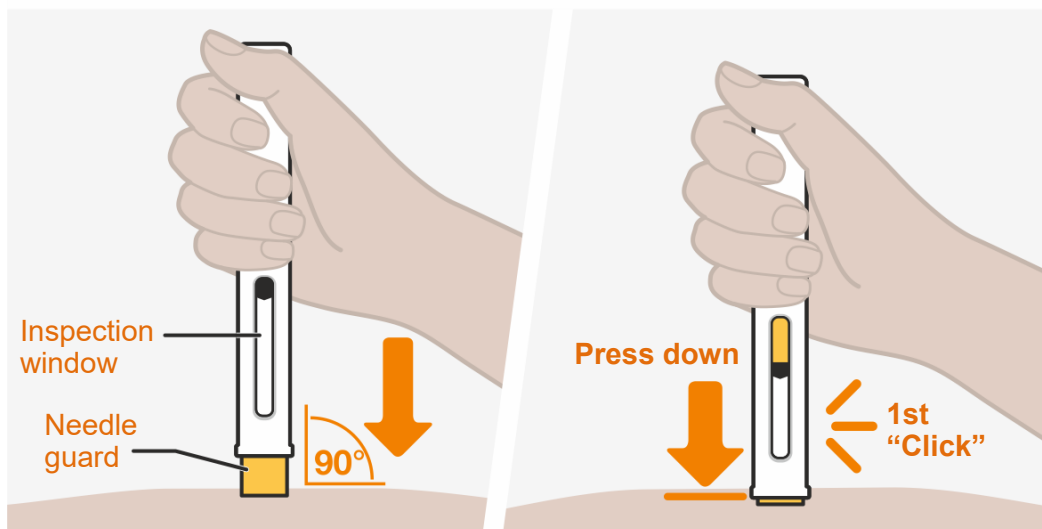
- Wash your hands with soap and water.
 - Clean your injection site by wiping the skin with an alcohol wipe and allowing the skin to air dry.
- Do not** touch your injection site again until you have finished your injection.

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 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 autoinjector too soon and may cause a needle injury.
- After removal, do not put the needle cap back onto the autoinjector, as it may accidentally start the injection.

6. Start your injection

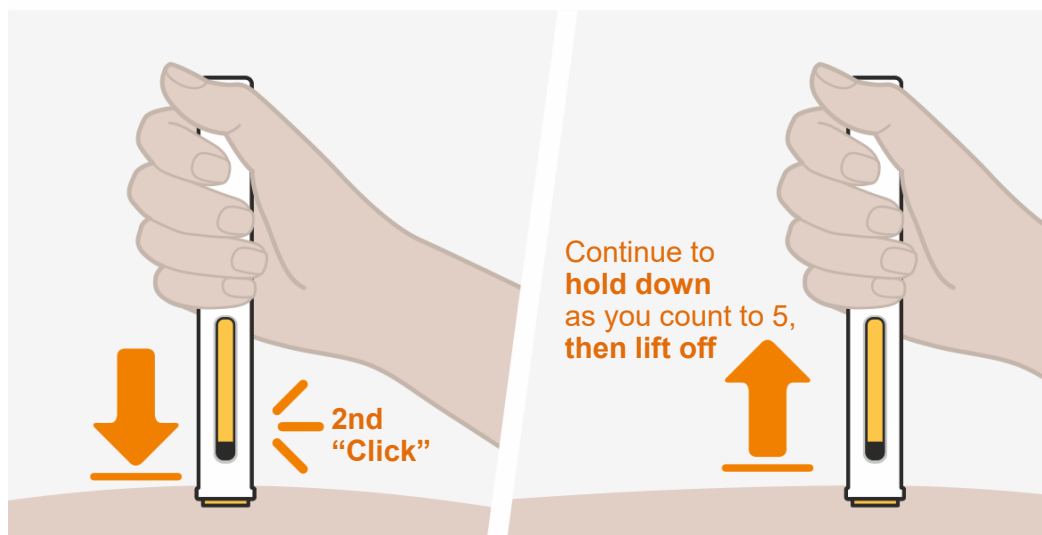


- Hold the autoinjector with its inspection window facing towards you, so you can see it, and with the yellow needle guard facing down.
- Place the autoinjector straight onto your injection site with the yellow needle guard flat against the surface of your skin, as shown.
- To start your injection, push the autoinjector down all the way and keep it held down against your skin. The yellow needle guard will slide up into the autoinjector.
- 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 autoinjector 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 autoinjector if the yellow needle guard doesn’t slide up as described. Dispose of it (see **Dispose of the used autoinjector** step), and start again with a new autoinjector.

7. Hold the autoinjector in place to complete your injection



- Continue to hold the autoinjector 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 autoinjector in place while you count to 5. Then lift the autoinjector 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 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.

8. Dispose of the used autoinjector

- Dispose of the used autoinjector and needle cap according to local requirements. Ask your doctor, nurse or pharmacist for advice if necessary.
- Keep your used autoinjectors and needle caps out of the reach of children.

NUCALA (mepolizumab injection)

INSTRUCTIONS FOR USE – 100 mg/mL PRE-FILLED SYRINGE (SAFETY SYRINGE)

Administer once every four weeks

These INSTRUCTIONS FOR USE should be read together with the rest of the PATIENT MEDICATION INFORMATION in your Nucala package. Contact your healthcare professional if you have any questions about Nucala.

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

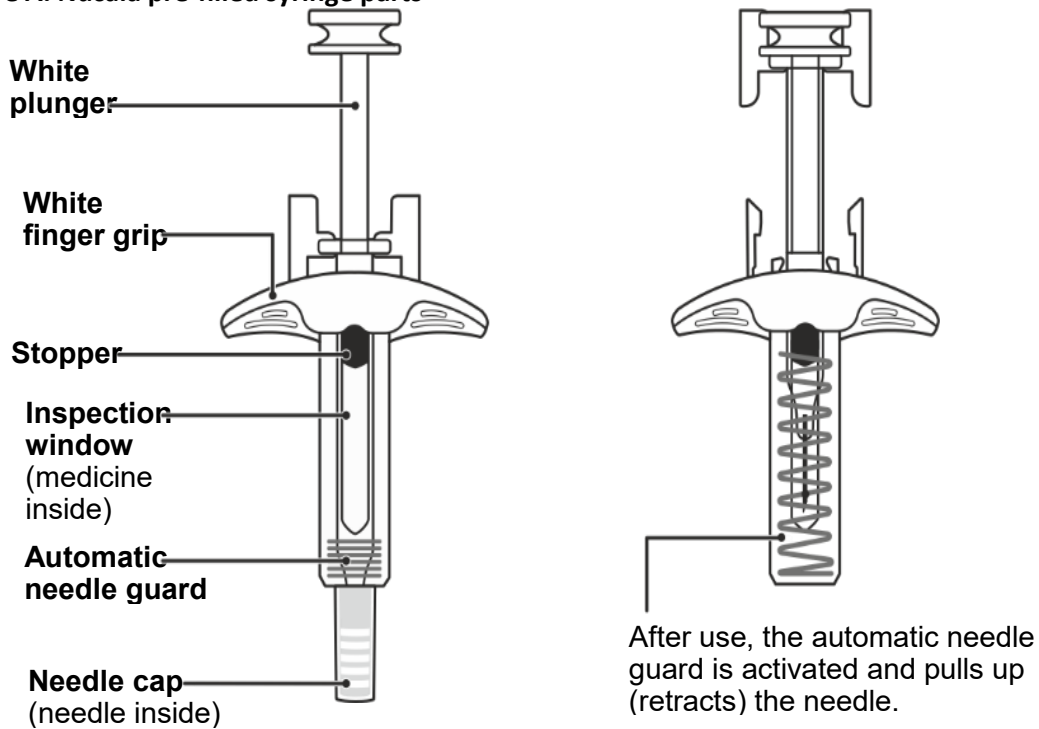
- Keep refrigerated before use.
- Do not freeze.
- Keep in the carton to protect from light.
- Keep out of the sight and reach of children.
- If necessary, the pre-filled safety syringe may be kept at below 30°C, for no more than 7 days, when stored in the original carton. Throw it away if it has not been used within 7 days.
- The pre-filled syringe must be used within 8 hours once the carton is opened. Discard if not used within 8 hours.
- Do not store it above 30°C.

Before you use Nucala

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

- **Do not** share your Nucala pre-filled safety 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.

Figure A. Nucala pre-filled syringe parts

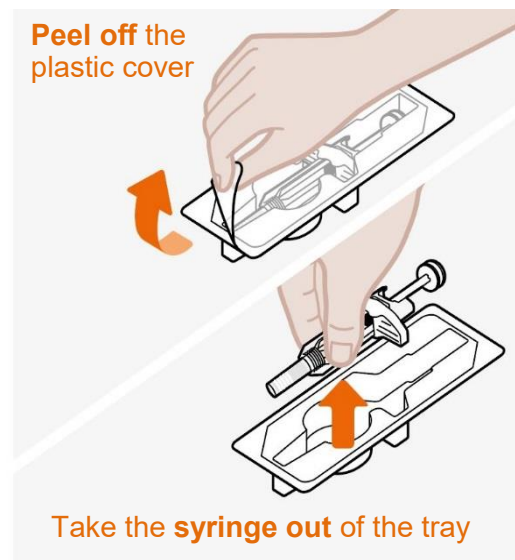
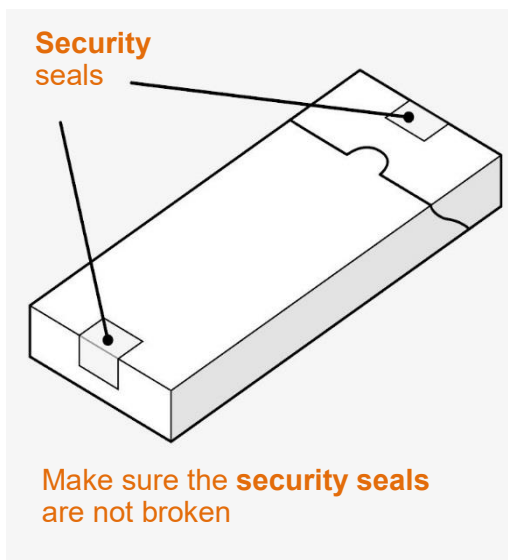


Gather Supplies

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 ball (not included)

1. Prepare the Nucala pre-filled syringe



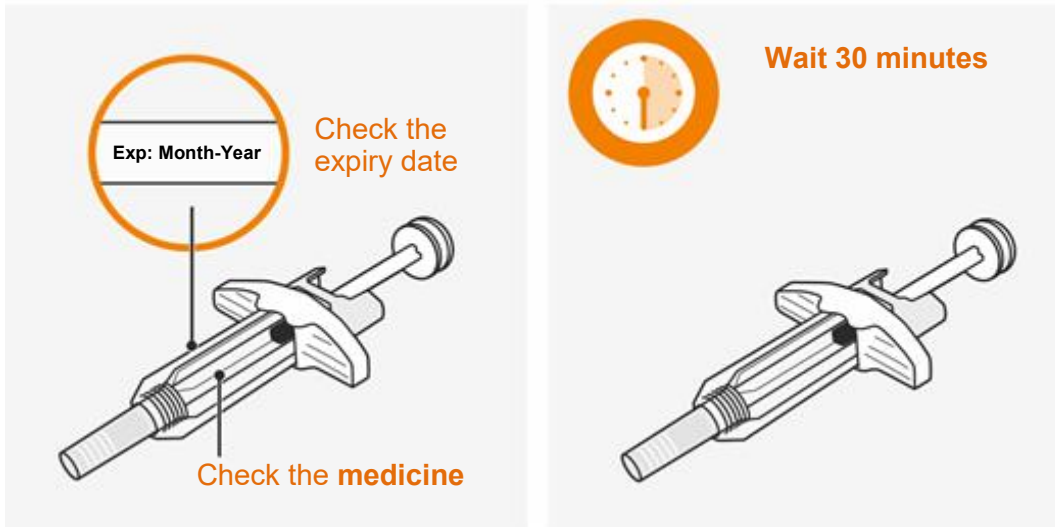
- Take the carton out of the refrigerator. Check the security seals are not broken.

- 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.

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.

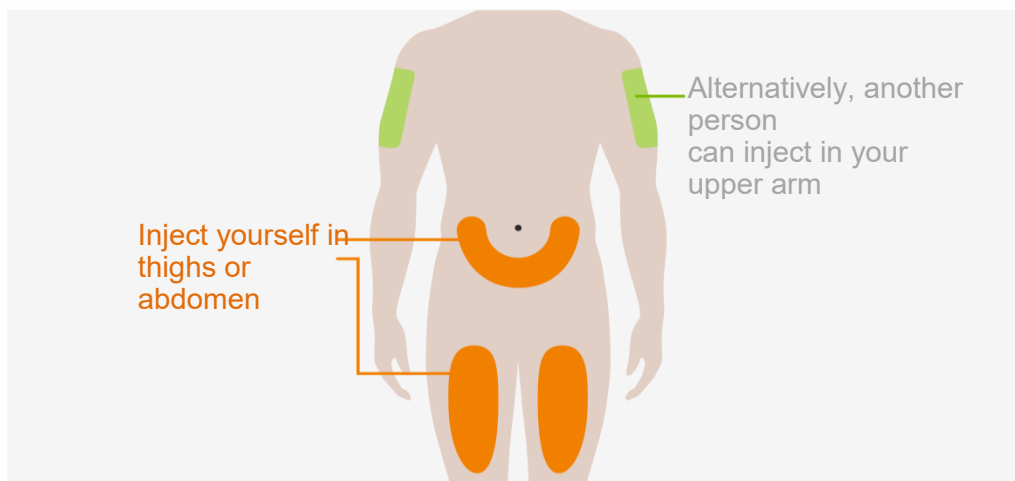
Do not warm the syringe in a microwave, hot water, or direct sunlight.

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.

3. Choose your injection site

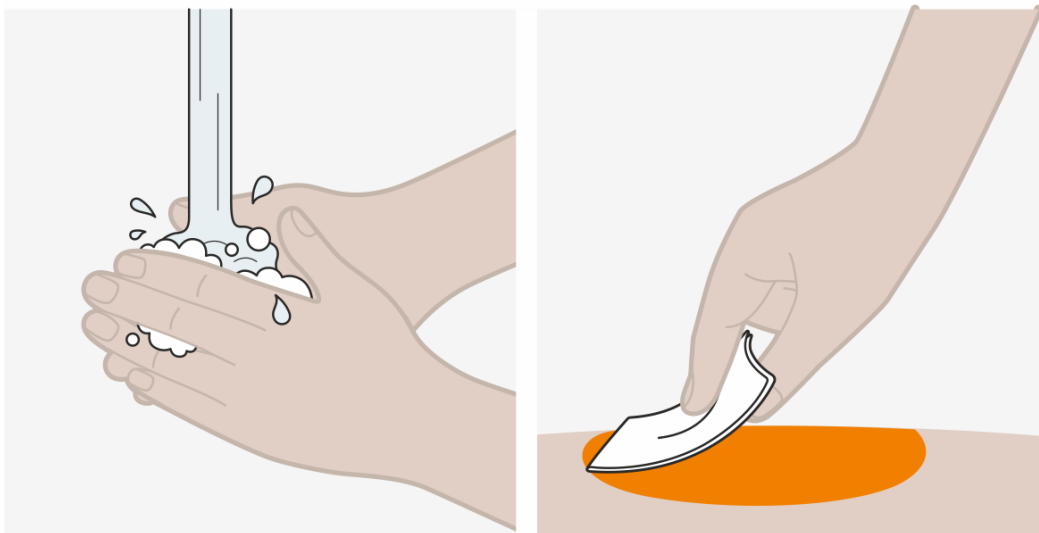


- You can inject Nucala into your thighs or abdomen.
- If someone else gives you the injection, they can also use your upper arm.
- If you need more than one injection to complete your dose then leave at least 5 cm (2 inches) between each injection site.

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 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.

5. 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.

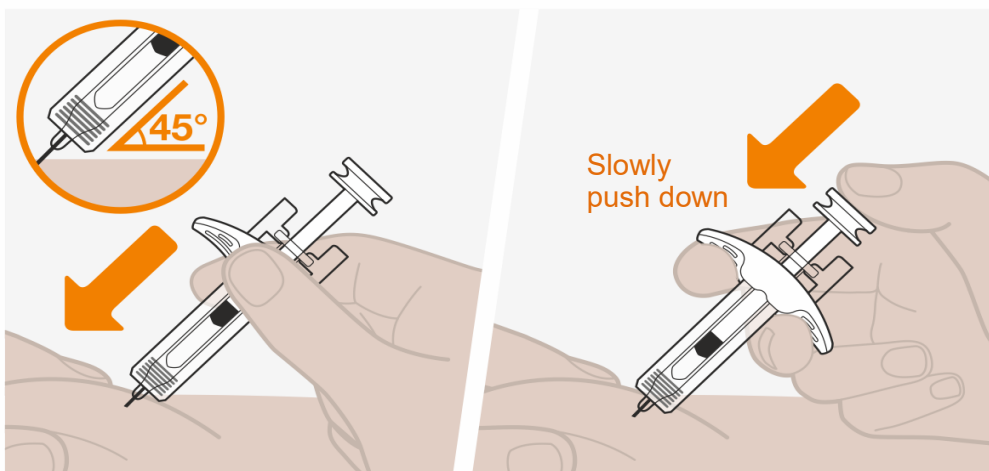
Do not touch the needle.

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.

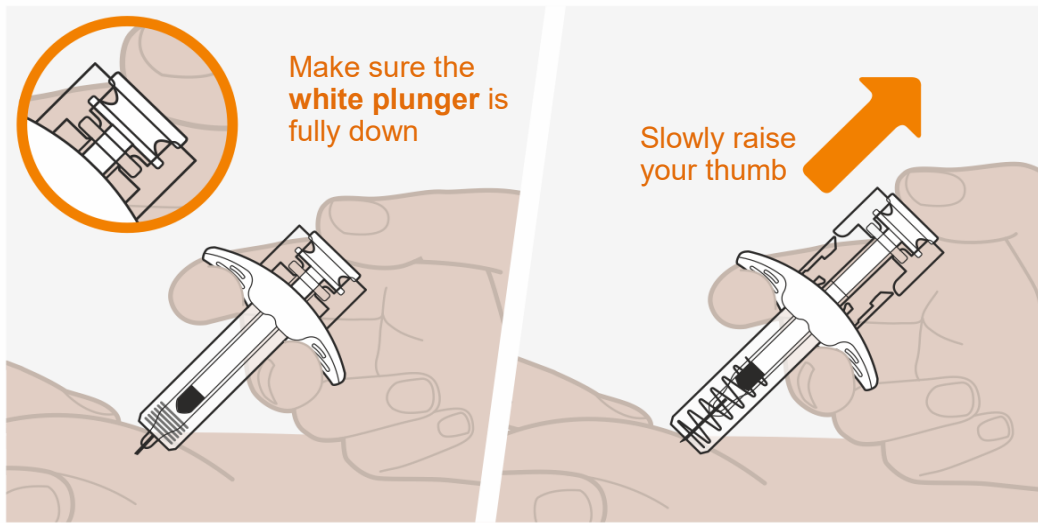
Do not put the needle cap back onto the syringe. This could cause a needle injury.

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.

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.

8. Dispose of the used syringe

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

NUCALA (mepolizumab injection)

INSTRUCTIONS FOR USE – 40 mg/0.4 mL PRE-FILLED SYRINGE (SAFETY SYRINGE)

Administer once every four weeks

These INSTRUCTIONS FOR USE should be read together with the rest of the PATIENT MEDICATION INFORMATION in your Nucala package. Contact your healthcare professional if you have any questions about Nucala.

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

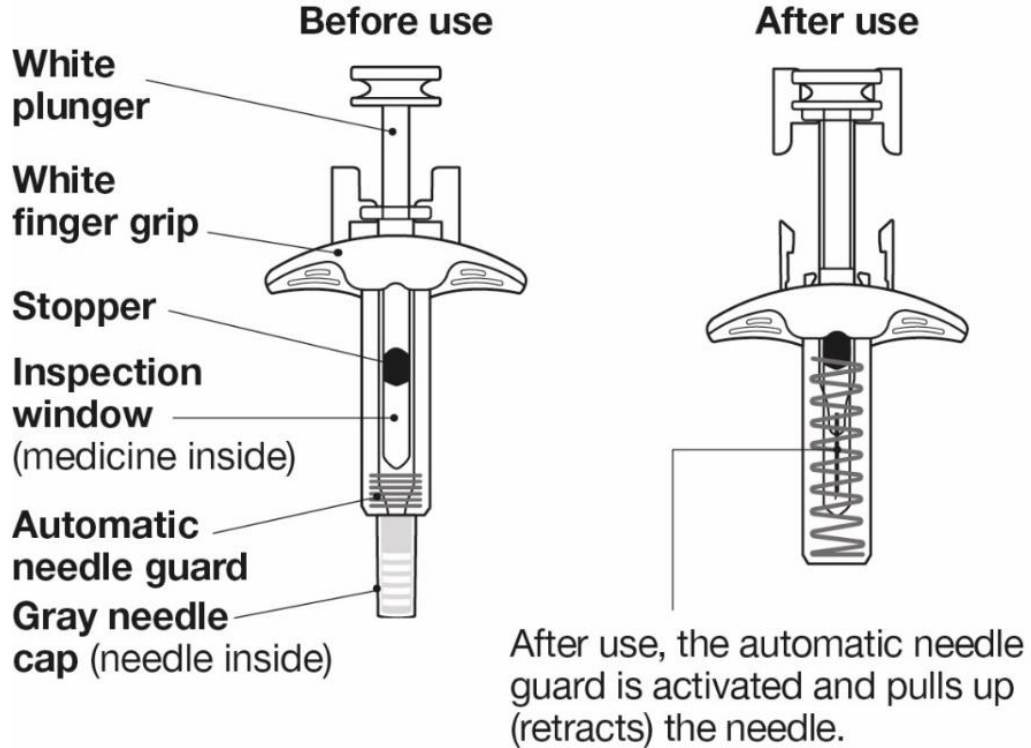
- Keep refrigerated before use.
- Do not freeze.
- Keep in the carton to protect from light.
- Keep out of the sight and reach of children.
- If necessary, the pre-filled syringe may be kept at below 30°C, for no more than 7 days, when stored in the original carton. Throw it away if it has not been used within 7 days.
- The pre-filled syringe must be used within 8 hours once the carton is opened. Discard if not used within 8 hours.
- Do not store it above 30°C.

Before you use Nucala

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

- **Do not** share the 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 the injection.

Figure A. Nucala pre-filled syringe parts

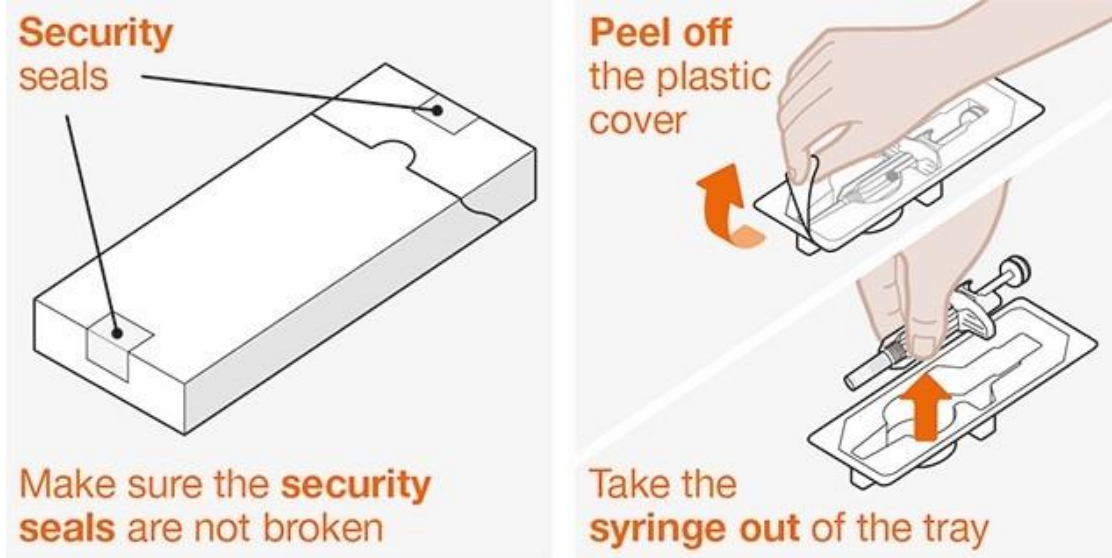


Gather Supplies

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 ball (not included)

1. Prepare the pre-filled syringe

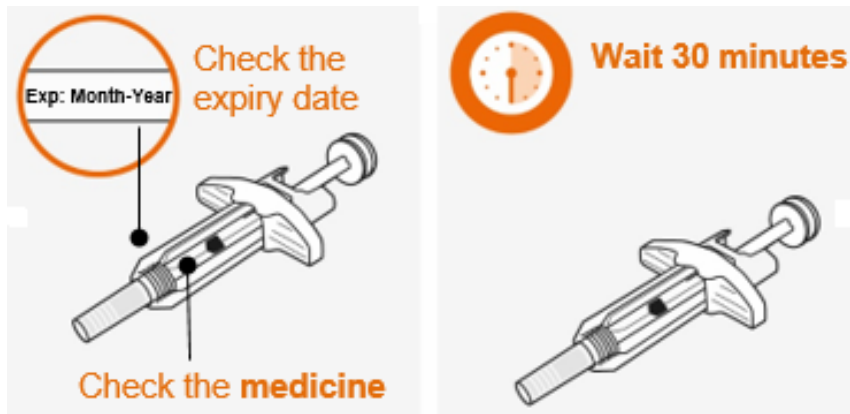


- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel back the film cover from the tray.
- Holding the middle of the syringe, carefully take it out of the tray.
- Place the syringe on a clean, flat surface, at room temperature, away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

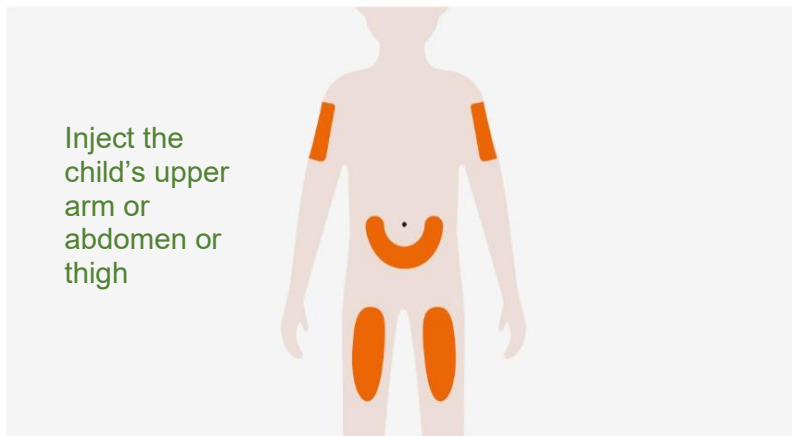
2. Inspect and wait 30 minutes before use



- 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.

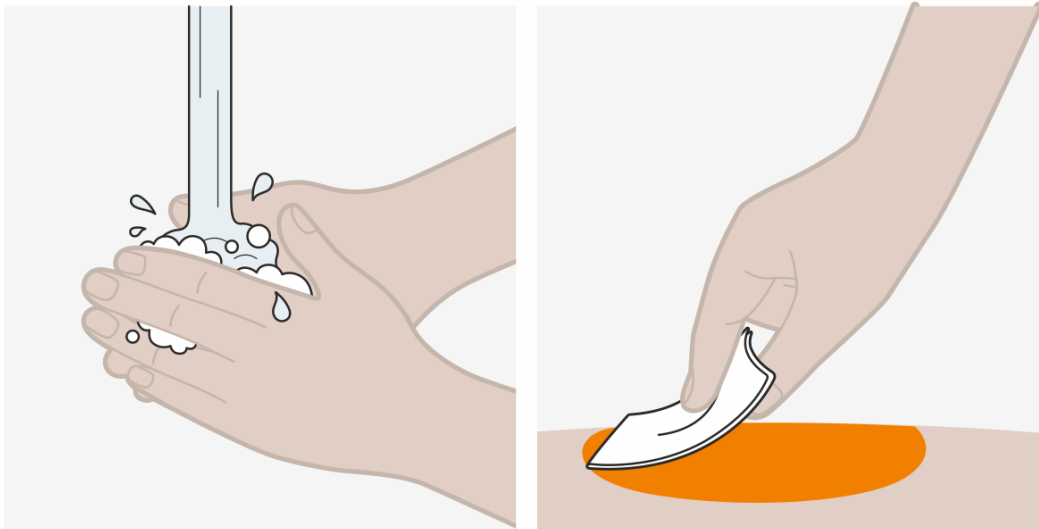
- Do not** use if the expiry date has passed.
- Do not** warm the syringe in a microwave, hot water, or direct sunlight.
- Do not** inject if the solution looks cloudy or discoloured, or has particles.
- Do not** use the syringe if left out of the carton for more than 8 hours.
- Do not** remove the needle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

3. Choose the injection site



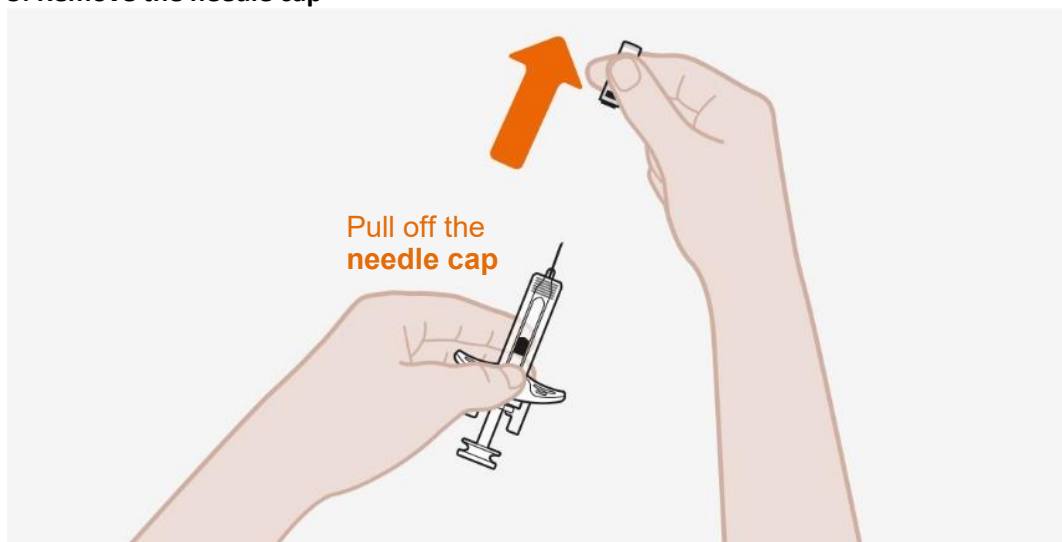
- You can inject Nucala into the upper arm, abdomen or thigh of the child you are caring for.
- Do not** inject where the skin is bruised, tender, red or hard.
Do not inject within 5 cm (2 inches) of the navel (belly button).

4. Clean the injection site



- Wash your hands with soap and water.
 - Clean the 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 the injection.

5. 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.

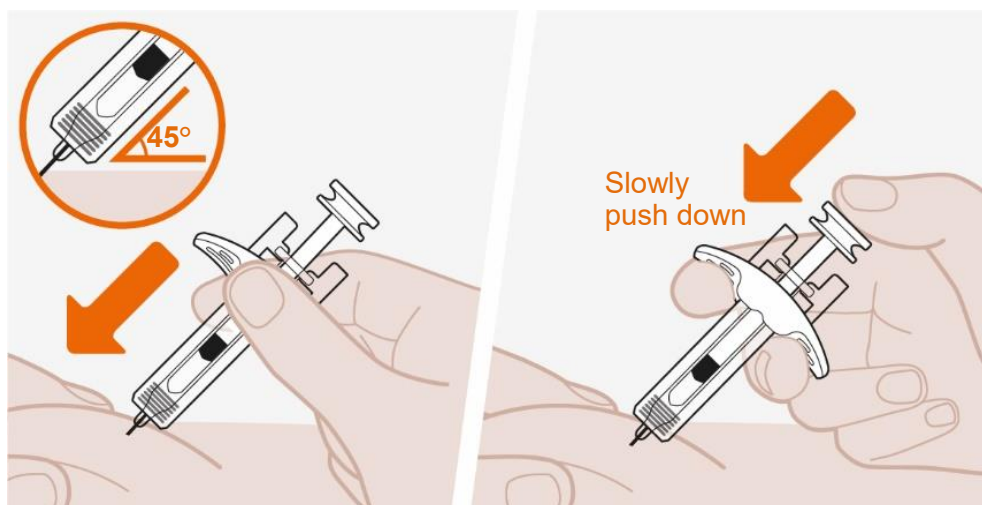
Do not touch the needle.

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

Do not expel any air bubbles from the syringe.

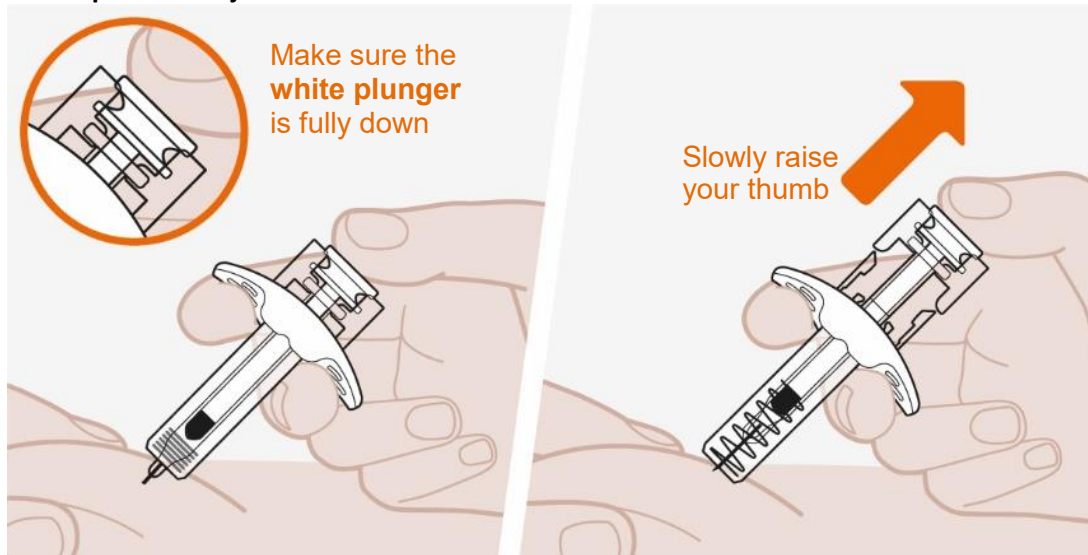
Do not put the needle cap back onto the syringe. This could cause a needle injury.

6. Start the injection



- Use your free hand to pinch the skin around the 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 the full dose.

7. Complete the 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.

8. Dispose of the used syringe

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