

NUCALA 100MG/ML SOLUTION FOR INJECTION IN PRE-FILLED PEN (AUTOINJECTOR)

Mepolizumab 100mg/ml

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What NUCALA is used for

NUCALA contains the active substance **mepolizumab**, a *monoclonal antibody*, a type of protein designed to recognize a specific target substance in the body. It is used to treat severe eosinophilic asthma in patients 12 years and older. NUCALA is also used to treat relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA) and CRSwNP (Chronic Rhinosinusitis with Nasal Polyps) in adult patients aged 18 years and over.

How NUCALA works

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

Severe eosinophilic asthma

Some people with severe asthma have too many *eosinophils* (a type of white blood cell) in the blood and lungs.

This condition is called *eosinophilic asthma* – the type of asthma NUCALA can treat.

NUCALA can reduce your number of asthma attacks, if you or your child are already using medicines such as high dose

inhalers, but your asthma is not well controlled by these medicines.

Eosinophilic granulomatosis with polyangiitis (EGPA)

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

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

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

CRSwNP is a condition in which people have too many eosinophils 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, relieves your nasal congestion and helps prevent surgery for nasal polyps.

NUCALA can also help reduce the need for oral corticosteroids to control your symptoms.

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

Before you use NUCALA

When you must not use it

If you are allergic to mepolizumab or any other ingredients of NUCALA

Before you start to use it

Before you use NUCALA your doctor needs to know:

- Medicines of this type (monoclonal antibodies) can cause severe allergic reactions when injected into the body. Check with your doctor if you think this may apply to you.
- NUCALA may weaken your resistance to infections caused by parasites. If you have a parasitic infection, it should be treated before you start treatment with NUCALA.

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

If you are pregnant, or think you could be, or if you are planning to become pregnant, don't take NUCALA without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking NUCALA while you're pregnant.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicine bought without a prescription.

How to use NUCALA

How much to use

NUCALA is a solution for injection in pre-filled pen (auto-injector) (which can be

given either by you, your caregiver or a doctor/nurse).

NUCALA is given by injection under your skin (subcutaneous injection)
Your doctor or nurse will decide if you or your caregiver can inject NUCALA. If appropriate, they will then provide training to show you or your caregiver the correct way to use NUCALA.

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

Severe eosinophilic asthma

Adult and adolescents aged 12 years and older:

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

Eosinophilic granulomatosis with polyangiitis (EGPA)

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

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

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

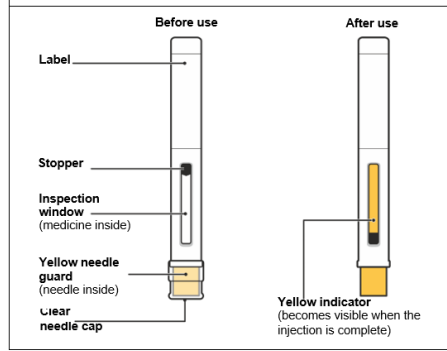
The injection sites should be at least 5 cm apart.

Step-by-step instructions:

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

Follow these instructions on how to use the pre-filled pen (autoinjector). Failure to follow these instructions may affect proper function of the pre-filled pen (autoinjector).

Know your pre-filled pen

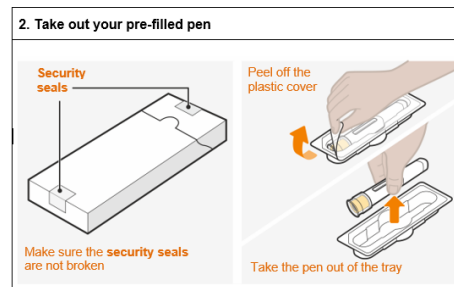


Nine important things you need to know about NUCALA

1. Get ready what you need

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

2. Take out your pre-filled pen

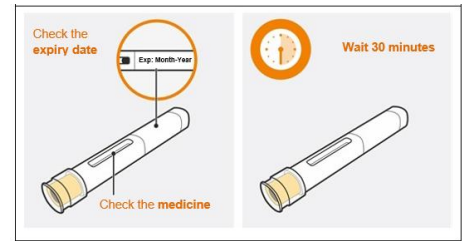


- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel back the film cover from the tray.
- Holding the middle of the pen, carefully take it out of the tray.
- Place the pen on a clean, flat surface, at room temperature, away from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

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

Do not remove the needle cap at this stage.

3. Inspect and wait 30 minutes before use



- Check the expiry date on the label of the pen.
- Look in the inspection window to check that the liquid is clear (free from cloudiness or particles) and colorless 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.

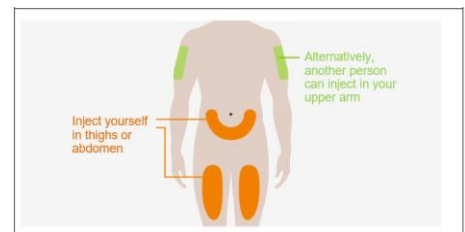
Do not warm the pen in a microwave, hot water, or direct sunlight.

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

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

Do not remove the needle cap during this step.

4. Choose your injection site

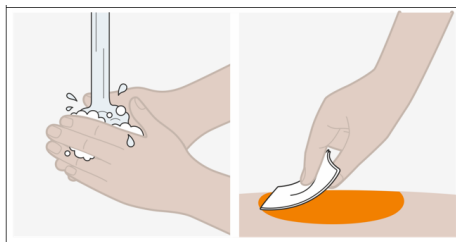


- You can inject NUCALA into your thighs or abdomen.
- If someone else gives you the injection, they can also use your upper arm.
- If you need more than one injection to complete your dose, then leave at least 5 cm between each injection site.

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

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

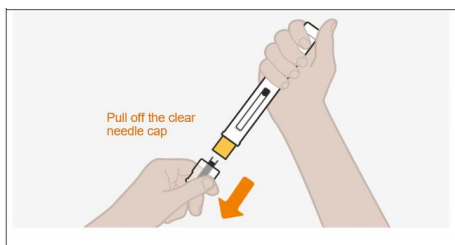
5. Clean your injection site



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

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

6. Remove the clear needle cap

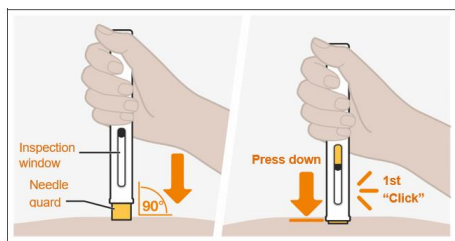


- Remove the clear needle cap from the pen by firmly pulling it straight off.
- Do not worry if you see a drop of liquid at the end of the needle. This is normal.
- Inject straight after removing the needle cap, and **always** within 5 minutes.

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 the injection



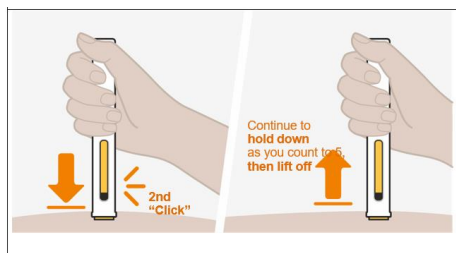
- Hold the pen with its inspection window facing towards you, so you can see it, and with the yellow needle guard facing down.

- 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 the 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.

9. Dispose of the used pen

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

When to use it

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

This will treat your symptoms throughout the day and night.

How long to use it

Don’t stop NUCALA without advice. Do not stop injections of NUCALA unless your doctor advises you to. Interrupting or stopping the treatment with NUCALA may cause your symptoms to come back.

Take NUCALA for as long as your doctor recommends. Don’t stop unless your doctor advises you to.

If you forget to use it

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

If you use too much (overdose)

If you have injected too much NUCALA, contact your doctor or pharmacist for advice. If possible, show them the NUCALA pack.

While you are using NUCALA

Things you must do

Always use NUCALA exactly as your doctor has told you to. Don’t exceed the

recommended dose. Check with your doctor or pharmacist if you're not sure.

Things you must not do

This medicine has been prescribed for you personally. Don't pass it on to other people – it may harm them even if their symptoms seem to be the same as yours.

Things to be careful of

Conditions you need to look out for

Allergic reactions, which may be severe (e.g. anaphylaxis) to NUCALA are rare (they may affect up to 1 in 1000 people). If you have any of the following symptoms after taking NUCALA:

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

Contact a doctor immediately if you get any of these symptoms. Stop taking NUCALA.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects caused by NUCALA are usually mild to moderate but can occasionally be serious.

Very common side effects

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

- headache

Common side effects

These may affect **up to 1 in 10** people:

- chest infection- symptoms of which may include cough and fever (high temperature)
- urinary tract infection (blood in urine, painful and frequent urination, fever, pain in lower back)
- upper abdominal pain (stomach pain or discomfort in the upper area of the stomach)

- fever (high temperature)
- eczema (itchy red patches on the skin)
- injection-site reaction (pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given)
- back pain
- pharyngitis (sore throat)
- nasal congestion (stuffy nose)

Rare side effects

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

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

If you get side effects

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of NUCALA

Storage

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

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

Store in refrigerator (2-8°C). Do not freeze. Store in the original carton to protect from light.

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

The pre-filled pen must be administered within 8 hours once the pack is opened. Discard if not administered within 8 hours.

Disposal

If you have any unwanted NUCALA, don't dispose of them in your wastewater or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product description

What it looks like

NUCALA is supplied as a 1 mL clear to opalescent, colourless to pale yellow to pale brown solution in a single use pre-filled pen (auto-injector).

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

Ingredients

Active ingredient(s)
Mepolizumab

Inactive ingredient(s)
Sucrose, Sodium phosphate dibasic heptahydrate, Citric acid monohydrate, Polysorbate 80, EDTA disodium dehydrate and Water for Injection

MAL number

MAL22096010ARZ

Manufactured and released by

Glaxo Operations UK Ltd (Trading as Glaxo Wellcome Operations). Harmire Road, Barnard Castle, DL12 8DT, United Kingdom.

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn Bhd HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor, Malaysia.

Date of revision

12/12/2024

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