Package leaflet: Information for the user

Nucala 100 mg powder for solution for injection
mepolizumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

1. What Nucala is and what it is used for

Nucala contains the active substance **mepolizumab,** a *monoclonal antibody*, a type of protein designed to recognise a specific target substance in the body. It is used to treat **severe asthma** and **EGPA** (Eosinophilic Granulomatosis with Polyangiitis) in adults, adolescents and children aged 6 years and older. It is also used to treat **CRSwNP** (Chronic Rhinosinusitis with Nasal Polyps) and **HES** (Hypereosinophilic syndrome) in adults.

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

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 and tissue lining the 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.

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.

Hypereosinophilic syndrome (HES)

Hypereosinophilic 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**.**
Nucala helps reduce your symptoms and prevents flares. If you are taking medicines often referred to as *oral corticosteroids,* Nucala can also help reduce the daily dose you need to control your HES symptoms/flares.

2. What you need to know before you use Nucala

Do not use Nucala:
- if you are **allergic** to mepolizumab or any of the other ingredients of this medicine (listed in section 6).

➔ **Check with your doctor** if you think this applies to you.

Warnings and precautions
Talk to your doctor before using this medicine.

Worsening asthma
Some people get asthma-related side effects, or their asthma may become worse, during treatment with Nucala.

➔ **Tell your doctor or nurse** if your asthma remains uncontrolled, or gets worse, after you start Nucala treatment.

Allergic and injection site reactions
Medicines of this type *(monoclonal antibodies)* can cause severe allergic reactions when injected into the body (see section 4, 'Possible side effects').

If you may have had a similar reaction to any injection or medicine,

➔ **Tell your doctor before you are given Nucala**.

Parasitic infections

Nucala may weaken your resistance to infections caused by parasites. If you already have a parasitic infection; it should be treated before you start treatment with Nucala. If you live in a region where these infections are common or if you are travelling to such a region:

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

Children

Severe eosinophilic asthma and EGPA

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

CRSwNP and HES

This medicine is not intended for use in **children or adolescents below 18 years of age** for the treatment of CRSwNP or HES.

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

Other medicines for asthma, CRSwNP, EGPA or HES

✘ **Don't suddenly stop taking** your existing medicines for your asthma,CRSwNP, EGPA or HES once you have started Nucala. These medicines (especially ones called *oral corticosteroids*) must be stopped gradually, under the direct supervision of your doctor and dependent on your response to Nucala.

Pregnancy and breast-feeding
If you are pregnant, if you think you may be pregnant or are planning to have a baby, **ask your doctor for advice** before using this medicine.

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

Driving and using machines
The possible side effects of Nucala are unlikely to affect your ability to drive or use machines.

Nucala contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 100 mg dose, i.e., that is to say essentially "sodium-free".

3. How to use Nucala

Nucala is given to you by a doctor, nurse or healthcare professional, as an injection just under the skin (subcutaneously).

Severe eosinophilic asthma

Adults and adolescents aged 12 years and over
The recommended dose for adults and adolescents is 100 mg. You will be given 1 injection every four weeks.

Children aged 6 to 11 years old

The recommended dose is 40 mg. You will be given 1 injection every four weeks.

CRSwNP

Adults
The recommended dose for adults is 100 mg. You will be given 1 injection every four weeks.

EGPA

Adults and adolescents aged 12 years and over
The recommended dose for adults and adolescents is 300 mg. You will have 3 injections every four weeks.

Children aged 6 to 11 years old

Children weighing 40 kg or more:
The recommended dose is 200 mg. You will be given 2 injections every four weeks.

Children weighing less than 40 kg:
The recommended dose is 100 mg. You will be given 1 injection every four weeks.

The injection sites should be at least 5 cm apart.

HES

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

The injection sites should be at least 5 cm apart.

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

Stopping treatment with Nucala
Do not stop receiving injections of Nucala unless your doctor advises you to. Interrupting or stopping the treatment with Nucala may cause your symptoms and attacks to come back.

If your symptoms get worse while receiving injections of Nucala
➔ Call your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Allergic reactions
Some people may have allergic or allergic-like reactions. These reactions may be common (they can affect **up to 1 in 10 people).** They usually occur within minutes to hours after the injection, but sometimes symptoms can start up to several days later.

Symptoms can include:

- chest tightness, cough, difficulty breathing
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)
- swelling of eyelids, face, lips, tongue or mouth
- hives
- rash

➔ **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 to any injection or medicine:

➔ **Tell your doctor** before you are given Nucala.

Other side effects include:

Very common:
may affect more than 1 in 10 people

- headache

Common:
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
- arthralgia (joint pain)
- pharyngitis (sore throat)
- nasal congestion (stuffy nose)

Uncommon:
may affect up to 1 in 100 people

- herpes zoster (shingles)

Rare:
may affect up to 1 in 1,000 people

- Severe allergic reactions (*anaphylaxis*)

➔ **Tell your doctor or a nurse immediately** if you get any of these symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme Website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Nucala

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

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

Store below 25°C.
Do not freeze.
Store in the original package to protect from light.

6. Contents of the pack and other information

What Nucala contains
The active substance is mepolizumab. Each vial contains 100 mg of mepolizumab.
After reconstitution, each ml of solution contains 100 mg mepolizumab.

The other ingredients are sucrose, sodium phosphate dibasic heptahydrate and polysorbate 80.

What Nucala looks like and contents of the pack

Nucala is a lyophilised white powder supplied in a clear, colourless glass vial with a rubber stopper.

Nucala is available in a pack containing 1 vial, or in multipacks with 3 individual vials.

Marketing Authorisation Holder
GlaxoSmithKline UK Limited
79 New Oxford Street
London
WC1A 1DG
United Kingdom

Manufacturer
GlaxoSmithKline Manufacturing S.P.A
Strada Provinciale Asolana, No 90
43056 San Polo di Torrile, Parma
Italy

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name **Nucala 100mg powder for solution for injection**
Reference number 19494/0285

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 02/2025

The following information is intended for healthcare professionals only:

7. Step-by-step instructions for use and handling, reconstitution, and administration

Nucala is provided as a lyophilised, white powder in a single-use vial for subcutaneous injection only. Reconstitution should be carried out under aseptic conditions.

Once reconstituted, Nucala will contain a concentration of 100 mg/mL mepolizumab. The solution for injection can be stored between 2°C to 30°C for no more than 8 hours. Any unused concentrate or solution remaining after 8 hours must be discarded.

Traceability

In order to improve traceability of the biological medicinal products, the name and batch number of the administered product should be clearly recorded.

Instructions for reconstitution for each vial

1. **Reconstitute the contents of the vial with 1.2 mL of sterile water for injections** preferably using a 2 to 3 ml syringe and a 21 gauge needle. The stream of sterile water should be directed vertically, onto the centre of the lyophilised cake. Allow the vial to sit at room temperature during reconstitution, gently swirling the vial for 10 seconds with circular motion at 15-second intervals until the powder is dissolved.

   *Note: The reconstituted solution **must not be shaken** during the procedure as this may lead to product foaming or precipitation. Reconstitution is typically complete within 5 minutes after the sterile water has been added, but it may take additional time.*

2. If a mechanical reconstitution device (swirler) is used to reconstitute Nucala, reconstitution can be accomplished by swirling at 450 rpm for no longer than 10 minutes. Alternatively, swirling at 1000 rpm for no longer than 5 minutes is acceptable.
3. Following reconstitution, Nucala should be visually inspected for particulate matter and clarity prior to use. The solution should be clear to opalescent, and colourless to pale yellow or pale brown, free of visible particles. Small air bubbles, however, are expected and acceptable. If particulate matter remains in the solution or if the solution appears cloudy or milky, the solution must not be used.
4. The reconstituted solution, if not used immediately must be:
   - Protected from sunlight
   - Stored below 30°C, not frozen
   - Discarded if not used within 8 hours of reconstitution

Instructions for administration of 100 mg dose

1. For subcutaneous administration, a 1 mL polypropylene syringe fitted with a disposable needle 21 gauge to 27 gauge x 0.5 inch (13 mm) should preferably be used.
2. Just prior to administration, remove 1 mL of reconstituted Nucala from one vial. Do not shake the reconstituted solution during the procedure as this could lead to product foaming or precipitation.
3. Administer the 1 mL injection (equivalent to 100 mg mepolizumab) subcutaneously into the upper arm, thigh, or abdomen.

If more than one vial is required for administration of the prescribed dosage, repeat steps 1 to 3. It is recommended that individual injection sites are separated by at least 5 cm.

Instructions for administration of 40 mg dose

1. For subcutaneous administration, a 1 mL polypropylene syringe fitted with a disposable needle 21 gauge to 27 gauge x 0.5 inch (13 mm) should preferably be used.

2. Just prior to administration, remove 0.4mL of reconstituted Nucala. Do not shake the reconstituted solution during the procedure as this could lead to product foaming or precipitation. Dispose of the remaining solution.
3. Administer the 0.4mL injection (equivalent to 40 mg mepolizumab) subcutaneously into the upper arm, thigh, or abdomen.

Disposal

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