Nucala (mepolizumab)

Your guide to Nucala

for Eosinophilic Granulomatosis with Polyangiitis (EGPA)

For New Zealand residents only.

This item is intended for EGPA patients who have been prescribed Nucala for injection at home. For full information, please refer to the Nucala Consumer Medicine Information.

Adverse events involving GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500.

Always read the Consumer Medicine Information before taking this medicine. If you have any questions, speak to your doctor, nurse or pharmacist.

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Welcome to NUCALA

This guide has been written for people like you, those with eosinophilic granulomatosis with polyangiitis (EGPA) who have been prescribed NUCALA.

NUCALA has been prescribed by your doctor as an add-on treatment to help reduce EGPA symptoms and delay a flare-up of these symptoms. Symptoms EGPA patients may experience include fatigue, muscle and joint pain, weight loss, nasal symptoms, and difficulty breathing.[1,5,6,7,8,9,11]

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

What is ***Eosinophilic Granulomatosis with Polyangiitis (EGPA)?***

Eosinophilic Granulomatosis with Polyangiitis

Eosinophilic granulomatosis (gran-u-lo-ma-toe-sis) with polyangiitis (poly-angi-i-tis) (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.[2,4,11]

EGPA most commonly affects the lungs and sinuses but often affects other organs including the skin, heart, kidneys, nerves or bowels.[3,11]

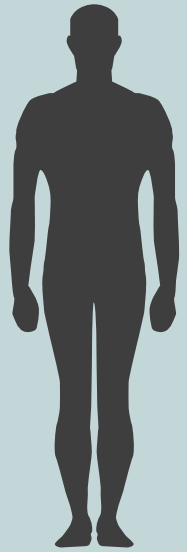
Role of inflammation in EGPA

The inflammation associated with EGPA is believed to be caused, in part, by an increase in eosinophils.[4] An eosinophil is a type of white blood cell that is a normal part of the body's immune system.[4,12,13,16]

When you have EGPA, the percentage of eosinophils can be higher than normal. The high numbers of eosinophils may cause inflammation and damage in your body.[4,12,13]

EGPA** can affect different **parts of the body[3,11]

- Lungs
- Heart
- Nerves
- Sinuses
- Skin
- Kidneys
- Bowels



***EGPA symptoms** include:*

- Fatigue (Feeling Tired)[5]
- Difficulty Breathing[5,7]
- Weight Loss[5,9]
- Muscle and Joint Pain[5,6]
- Nasal Sinus Symptoms[5,8]

What is NUCALA?

NUCALA is a medication indicated as an add-on treatment for relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA) in adult patients aged 18 years and over.[1]

Your doctor may assess the following before prescribing NUCALA:[1,5-9,11]

Other medications you are taking

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

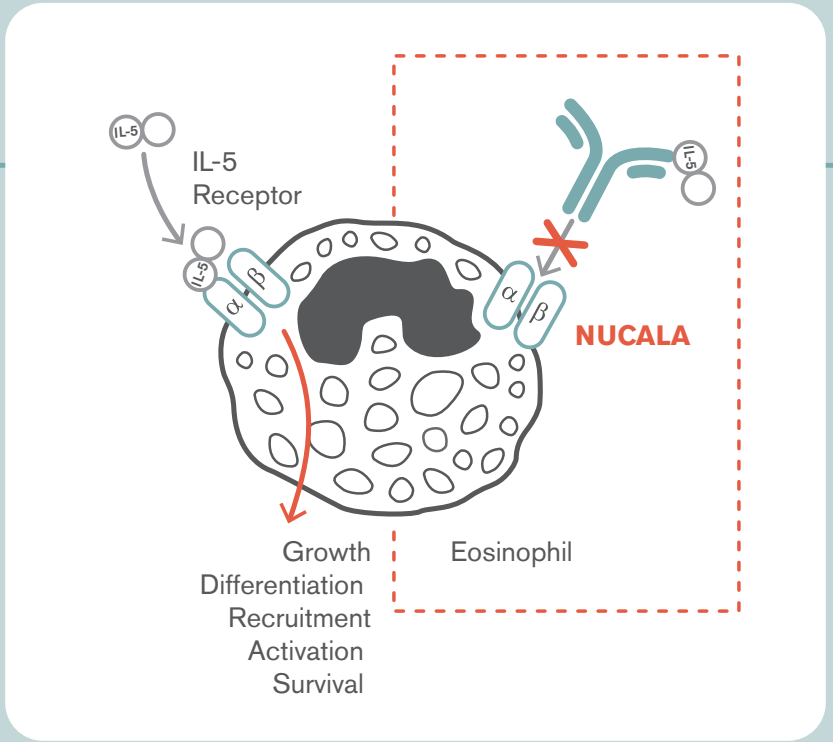
Your symptoms such as fatigue, muscle and joint pain, weight loss, nasal sinus symptoms, and difficulty breathing[5,6,7,8,9]

How does NUCALA work?

NUCALA contains the medicine mepolizumab (me-poh-liz-ooh-mab), which works by blocking a protein called interleukin-5 (IL-5).[1,11]

By blocking the action of IL-5, NUCALA:[11]

- Limits the production of more eosinophils in the bone marrow
- Lowers the number of eosinophils in the bloodstream and the lungs.



What are the benefits of NUCALA?[^1,10,11,14,15]

Longer

time in remission

Fewer

relapses

Lower

dose of oral corticosteroids (like prednisone)

^When compared with placebo. Your experience may be different.

Based on a 1-year clinical study, patients treated with NUCALA in combination with other medicines experienced^:

Longer time in remission (no active vasculitis, and a prednisone or prednisolone dose less than or equal to 4 mg per day)[10]

- Patients receiving NUCALA had longer time in remission
- More patients receiving NUCALA experienced remission within the first 6 months of treatment and stayed in remission for the remainder of the study

Fewer relapses (worsening symptoms that required increased steroid dose, and/or increase in dose or start of immunosuppressants, and/or hospitalisation)[10]

- Patients treated with NUCALA had about half the number of relapses per year

Lower dose of oral steroids (like prednisone)[10]

- Almost half of patients receiving NUCALA had their oral steroid dose reduced to 4 mg per day or less
- About 1 in 5 patients treated with NUCALA had their oral steroids stopped altogether

^When compared with placebo. Number of participants in the Nucala group=68; number of participants in the placebo group=68. Your experience may be different.

How is Nucala taken?[1,11]

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

Do not stop treatment with NUCALA unless advised by your doctor. Consult your healthcare professional if you have questions about your medication or medical condition.

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.

Tell your doctor if you are taking corticosteroids or other medicines for the treatment of EGPA. 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).

How will I receive Nucala?

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 at home or at a clinic
- The injection goes just **underneath the skin** (subcutaneously)[11]

Planning for your next dose

You might wonder how to remember your injection appointments.

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
- 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 is the recommended dose of NUCALA for EGPA?

Adults (≥18 years of age):
300 mg, given as 3 injections under the skin (subcutaneous) every 4 weeks.[1]

NUCALA in a pre-filled pen 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.

Frequently Asked Questions:[11]

What if I miss a dose?

You or your caregiver should inject the next dose of NUCALA as soon as you remember.

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 is NUCALA stored?

You need to keep it in the unopened original packaging and protected from light. You may keep NUCALA at room temperature, up to 30°C, for no more than 7 days when kept in the unopened 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 or if the carton is opened and not used within 8 hours.

Where can I receive further support?

If you have any questions, speak to your doctor, nurse or pharmacist.

What side effects can NUCALA cause?[1,11]

As with all medications, 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, including:

- **allergic (hypersensitivity) reactions, including anaphylaxis.** Serious allergic reactions can happen after you get your NUCALA injection. Allergic reactions can sometimes happen hours or days after you get a dose of NUCALA

The most common side effects of NUCALA in EGPA patients include: headache, joint pain, sinusitis, upper respiratory tract infection, nausea, injection site reactions, diarrhoea and vomiting.

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.

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

Your NUCALA injection tracker

Your doctor's name:		Your doctor's contact information:	
Date	**Time**	**Injection Site**	**Number of Doses taken**
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	
MM / DD / YY	☐ AM ☐ PM	☐ Upper arm ☐ Abdomen ☐ Thighs	

Nucala Important Safety Information[1]

Contraindications: hypersensitivity to mepolizumab or to any of the excipients. **Warnings & Precautions:** EGPA: NUCALA treated patients may experience a return of EGPA symptoms upon cessation of NUCALA and other EGPA treatments may need to be increased accordingly if NUCALA is discontinued as patients may decrease their other EGPA treatments during NUCALA treatment. **Adverse Reactions:** headache, joint pain, nausea, sinusitis, upper respiratory tract infection, diarrhoea, vomiting, injection site reaction. Please refer to the Nucala Consumer Medicine Information for more details.

References

1. GlaxoSmithKline New Zealand. Nucala Data Sheet. GSK NZ; 2023. Available at https://medsafe.govt.nz/profs/Datasheet/n/nucalainj.pdf.
2. Fagni, F.; et al. (2021). Front Med. 24(8):627776.
3. Fijolek, J. & Radzikowska, E. (2023). Front Med 10:1145257.
4. Gioffredi, A.; et al. (2014). Front Immunol 5:549.
5. Doubelt, I.; et al. (2021). ACR OpenRheumatol. 3(6): 404-412.
6. Mohammad, N. & Ghazali, W.S.W. (2017). BMJ Case Rep.
7. Cottin, V.; et al. (2016). Europ Respir Jour 48:1429-1441.
8. Low, M.C.; et al. (2019). Int Forum Allergy Rhinol. 10(2): 217-222.
9. Pagnoux, C., et al. (2007). Curr Opin Rheumatol 19(1): 25-32.
10. Wechsler M.E.; et al. (2017) N Engl J Med. 376:1921-1932.
11. GlaxoSmithKline New Zealand. Nucala Consumer Medicine Information. GSK NZ; 2023. Available at https://www.medsafe.govt.nz/Consumers/CMI.
12. Khoury P; et al. (2014) Nat Rev Rheumatol.10;474-483.
13. Vaglio A; et al. (2013) Allergy. 68;261-73.
14. Steinfeld J; et al. (2019) The Journal of Allergy and Clinical Immunology 143(6);2170-2177.
15. Wechsler ME; et al. (2017) N Engl J Med. 376;1921-1932 (supplementary).

Prescribing Information

Nucala (mepolizumab 100 mg) is a **Prescription Medicine**, available as a 100 mg/mL pre-filled pen (auto-injector). Each pre-filled pen delivers 100 mg mepolizumab in 1 mL. *Nucala* is used as an add-on treatment for; severe eosinophilic asthma in patients 12 years and over, severe chronic rhinosinusitis with nasal polyps (CRSwNP) with an inadequate response to intranasal corticosteroids in adult patients 18 years and older, relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA) in adult patients aged 18 years and over, and in adult patients with inadequately controlled hypereosinophilic syndrome (HES) without an identifiable non-haematologic secondary cause. *Nucala* is given by injection under your skin (subcutaneous). ***Nucala* is fully funded for severe eosinophilic asthma and EGPA only; Special Authority criteria apply. Use strictly as directed. *Nucala* has risks and benefits. Do not stop taking your other asthma medications including inhaled and /or oral steroid asthma medications. Tell your doctor if:** you have a parasitic (helminth) infection; you are taking prescription and over-the-counter medicines, vitamins, and herbal supplements; you are pregnant or plan to become pregnant; you are breastfeeding or plan to breastfeed. *Nucala* does not treat acute asthma symptoms, such as sudden asthma attack. Tell your healthcare professional or get emergency help immediately if you have any of the following symptoms of an allergic reaction: swelling of your face, mouth, and tongue, breathing problems, fainting, dizziness, feeling light-headed (low blood pressure), rash or hives. **Side effects:** headache, injection site reactions (pain, redness, swelling, itching, or a burning feeling at the injection site), back pain, and fatigue. Serious side effects may include allergic (hypersensitivity) reactions, including anaphylaxis. Serious allergic reactions can happen after you get your injection of *Nucala*. Allergic reactions can sometimes happen hours or days after you get a dose of *Nucala*. Herpes zoster infections that can cause shingles have happened in people who received *Nucala*. **If symptoms continue or you have side effects, see your doctor, pharmacist or health care professional.** For more information, see *Nucala* Consumer Medicine Information at www.medsafe.govt.nz. Ask your doctor if *Nucala* is right for you. Normal doctor's charges apply. **Adverse events involving GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500.**

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mepolizumab

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