

## Nucala (mepolizumab)

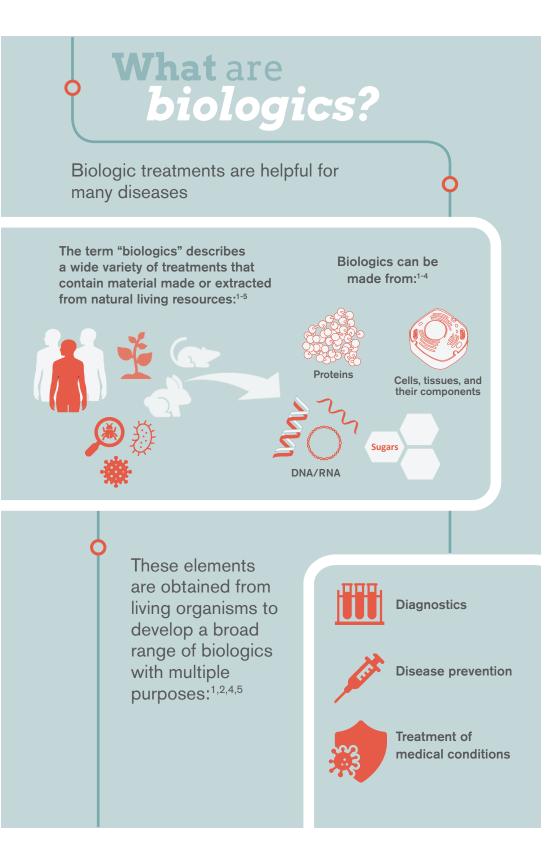
## An introductory booklet

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



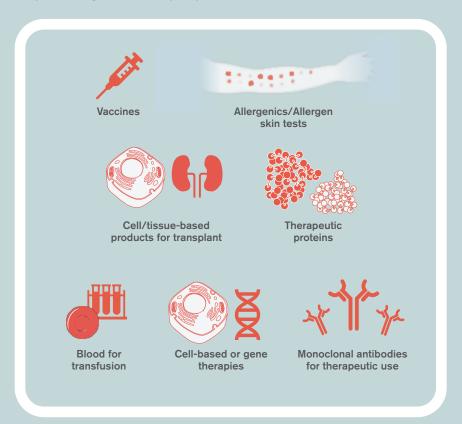
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Always read the Consumer Medicine Information before taking this medicine. If you have any questions, speak to your doctor, nurse or pharmacist.



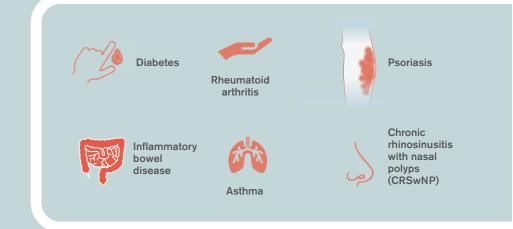
## **How** are biologics used?

Biologics come in a variety of forms, depending on their purpose.<sup>1-3,6</sup>



- A monoclonal antibody (or mAb) is derived from an individual immune cell, and targets one specific site on a protein – in this way, a mAb can be developed to target and neutralise one highly specific piece of a pathway.<sup>3,6-7</sup>
- Biologics in the form of mAbs have become available for a wide variety of medical conditions, providing targeted treatment options for patients.<sup>2,7</sup>

Various biologics have been used to treat diseases, including a wide variety of inflammatory disorders:<sup>3,6-9</sup>



In some cases, biologics might be prescribed when symptoms continue despite using standard/ traditional medications, and can be taken alongside other medications.<sup>7,9</sup>

 In the context of inflammatory diseases, a biologic may benefit a patient by specifically targeting an active inflammatory process and/or by preventing the pathological process from happening in the future.<sup>9</sup>

# What are nasal polyps?



Nasal polyps are inflammatory outgrowths coming from your nasal and sinus tissue. This booklet will focus on chronic rhinosinusitis with nasal polyps (CRSwNP), a type of chronic rhinosinusitis where these

Nasal congestion

growths occur. CRSwNP is very common, affecting ~1-4% of people across the United States and Europe.

The inflammation in CRSwNP is often characterised by increased numbers of a certain type of immune cell, called an eosinophil. Eosinophils play an important role in helping your body fight off infections. But for some people, too many eosinophils increase inflammation, driving disorders like CRSwNP.

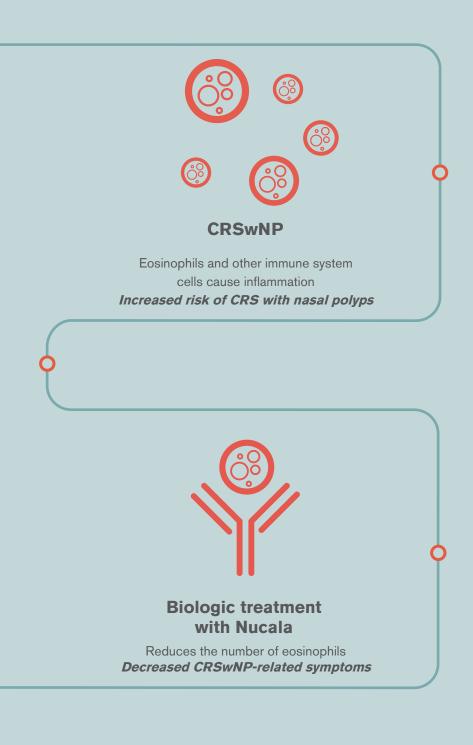
Since nasal polyps grow due to an underlying inflammatory issue, sometimes they come back, or recur - even after they have been surgically removed. People that have high levels of eosinophils in their body tend to be more likely to suffer from their nasal polyps recurring. High levels of eosinophils also tend to be related to worse symptoms of nasal polyps, such as:<sup>10</sup>





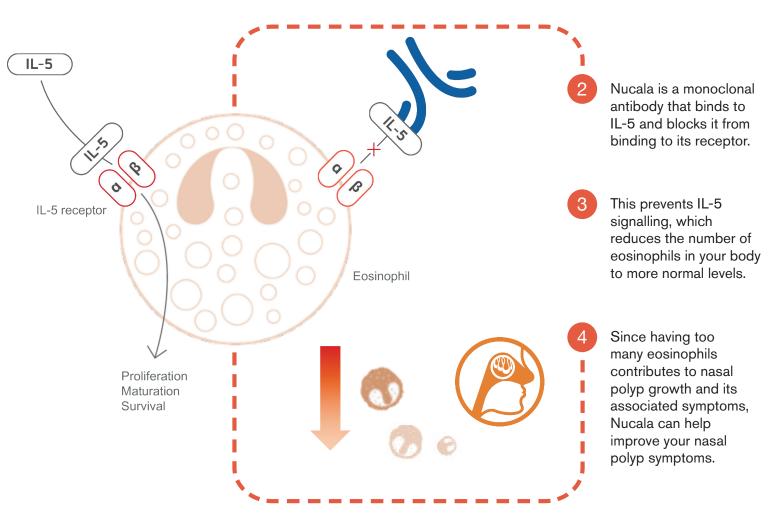
## How do biologics like Nucala treat chronic rhinosinusitis with nasal polyps?

Biologics like Nucala can reduce the number of eosinophils in the blood. Nucala is taken as an add-on medication for CRSwNP, as prescribed by your doctor - so you should continue taking your other medications for nasal polyps. In clinical studies, treatment with Nucala helped reduce the size of nasal polyps and the obstruction they cause. Improvements in other CRSwNP-related issues were also seen (such as reducing or delaying the need for an additional surgery).<sup>11,12</sup>



## How does Nucala work?

IL-5 is a type of signalling molecule called a cytokine. When it binds to its receptor, it leads to the growth and development of eosinophils, among other immune processes.



## So, how can Nucala help?

By reducing the number of eosinophils in your blood, Nucala may reduce your nasal polyps and their associated symptoms. Nucala may also help prevent surgery for nasal polyps. If you are taking oral steroids, Nucala may also help reduce the need for steroids to control your CRSwNP.



Reduce nasal polyp size and nasal obstruction

Reduce steroid use



Improve health-related quality of life



Improve loss of smell and other nasal symptoms

Reduce repeat sino-nasal surgery

## 0

Nucala is an ongoing treatment: to keep getting the benefits, you have to keep taking Nucala – even if you start to feel better. Nucala works as an add-on medication; you should continue taking your other medications for nasal polyps as prescribed by your doctor.

It can take time to see improvements. If you don't see benefits right away, keep taking your Nucala as directed by your doctor.

Remember: It's important that you report any side effects you experience to your doctor, nurse or pharmacist. See the back page for more information.



Nucala is given by injection, just under the skin (subcutaneous injection), rather than through an inhaler or in a tablet.

Injecting yourself might not be something you've done before, but if you and your doctor think it's right for you, you will be shown how to use the injection pen.

This kit is here to help give you the information you need – as is the support you'll receive from your doctor.

There's lots of information in the "Instructions for Use" brochure or in the quick-reference Frequently Asked Questions that are included in this kit. Read the package leaflet carefully before you start using this medicine, because it contains important information for you. If you have any questions, ask your doctor, nurse or pharmacist.

# Will there be side effects?

Like all medicines, Nucala can cause side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them. A very common side effect, which may affect more than 1 in 10 people, is headache. Common side effects, which may affect up to one in ten people, include injection-site reaction (pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given), eczema (itchy red patches on the skin), back pain, pharyngitis (sore throat), lower respiratory tract infection (congestion, cough, discomfort), nasal congestion (stuffy nose), upper abdominal pain (stomach pain or discomfort in the upper area of the stomach), urinary tract infection (blood in urine, painful and frequent urination, fever, pain in lower back), fever (high temperature).



Note that this is not a complete list of side effects, please refer to the Consumer Medicine Information for more details (available from www.medsafe.govt.nz).

## Where can I find out more

The following websites may be useful for additional information:

NUCALA PATIENT WEBSITE www.nucala.co.nz/np

HEALTH NAVIGATOR NZ www.healthnavigator.org.nz



## For more information, see the Frequently Asked Questions, which include answers to:

- I've found out I have chronic rhinosinusitis with nasal polyps. What does this mean?
- What is Nucala and how does it work?
- I've been prescribed Nucala to take at home. How often should I use it?
- How should I store my Nucala at home?
- How do I use my Nucala at home?
- How do I safely dispose of my Nucala?
- What if I miss a dose?
- How do I travel with my Nucala?
- How well will Nucala work?
- What possible side effects might I experience?
- Can I take Nucala if I am pregnant?
- Where can I receive further support?

## Glossary

- Biologic: a wide variety of treatments that contain material made or extracted from natural living resources, such as proteins, DNA/RNA, sugars, or cells, tissues, and their components
- Chronic rhinosinusitis with nasal polyps: an inflammatory condition resulting in sinus and nasal tissue outgrowths
- **Cytokine:** A signalling molecule that mediates multiple signalling processes
- **Eosinophil:** a specialised type of immune cell called a white blood cell
- **IL-5:** a type of cytokine involved in the growth and development of eosinophils, among other immune processes
- Monoclonal antibody: a type of blood protein derived from an individual immune cell that binds to one specific site on a target protein



## My next injections are on:





#### References

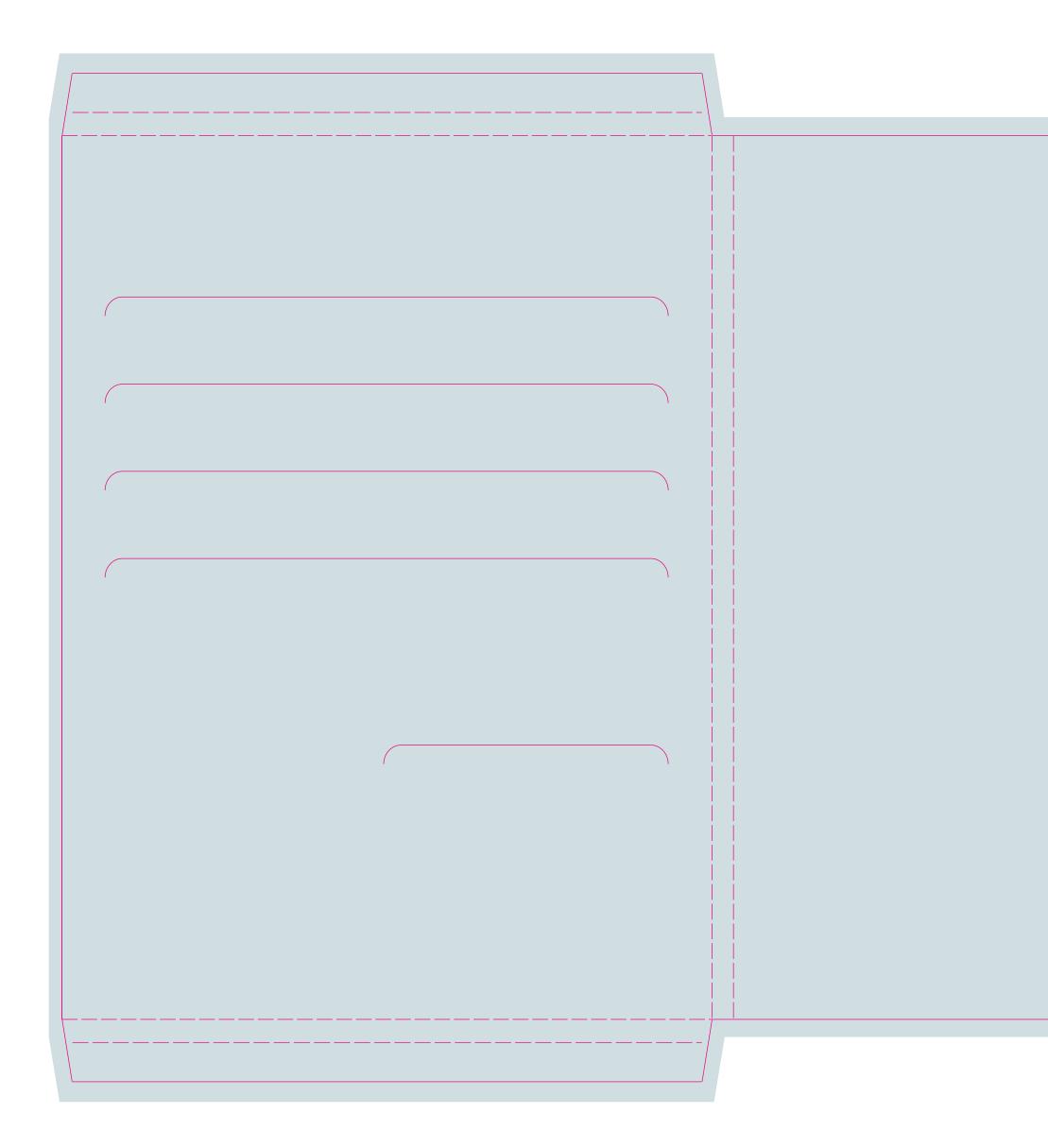
- 1. European Commission. What you Need to Know About Biosimilar Medicinal Products: Process on Corporate Responsibility in the Field of Pharmaceuticals Access to Medicines in Europe; A Consensus Information Document. 2013. https://www. medicinesforeurope.com/wp-content/uploads/2016/03/biosimilars\_report\_en.pdf [Accessed October 2021].
- 2. Food and Drug Administration. What Are "Biologics" Questions and Answers. Available from: https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers [Accessed October 2021].
- Noyes L. Corexcel.com. Online Continuing Education For Nurses: Big Biologics And MAbs...And The Increasing Immunosuppressed World. Available from: www.corexcel. com [Accessed October 2021].
- 4. Pharmaceutical Research and Manufacturers of America. Medicines in Development: Biologics. 2013. Available from: www.phrma.org [Accessed October 2021].
- 5. Ingrasciotta Y, et al. Safety of Biologics, Including Biosimilars: Perspectives on Current Status and Future Direction. *Drug Saf.* 2018;41(11):1013-1022.
- 6. Morrow T, Felcone LH. Defining the difference: What Makes Biologics Unique. *Biotechnol Healthc.* 2004;1(4):24-29.
- 7. American Academy of Allergy, Asthma & Immunology. Biologics for the Management of Severe Asthma. 2021. Available from: https://www.aaaai.org/tools-for-the-public/ conditions-library/asthma/biologics-for-the-management-of-severe-asthma [Accessed October 2021].
- 8. Bachert C, et al. Biologics For Chronic Rhinosinusitis With Nasal Polyps. *J Allergy Clin Immunol.* 2020;145:725-739.
- 9. Falla, KD. Veritas Health. Biologics: Basic Facts for Patients. 2017. Available from: https://www.arthritis-health.com/treatment/medications/biologics-basic-facts-patients 3/ [Accessed October 2021].
- 10. Laidlaw TM, et al. Chronic Rhinosinusitis with Nasal Polyps and Asthma. J Allergy Clin Immunol Pract. 2021;9(3):1133-1141.
- 11. GlaxoSmithKline New Zealand. Nucala Data Sheet. GSK NZ; 2023. Available at https://medsafe.govt.nz/profs/Datasheet/n/nucalainj.pdf.
- 12. GlaxoSmithKline New Zealand. Nucala Consumer Medicine Information. GSK NZ; 2022. Available at https://www.medsafe.govt.nz/consumers/cmi/n/nucalasolution.pdf



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Nucala (mepolizumab 100 mg) is a **Prescription Medicine**, available as a 100 mg powder for injection (100 mg/mL after reconstitution) and as a 100 mg/mL pre-filled pen (auto-injector). 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 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. Trademarks are owned by or licensed to the GSK group of companies. ©2024 GSK group of companies or its licensor. Marketed by GlaxoSmithKline NZ Limited, Auckland. Adverse events involving GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500. TAPS NP20375 PM-NZ-MPL-BKLT-240001 | Date of Approval: February 2024 Date of Expiry: February 2026.



## Nucala (mepolizumab)

Patient Starter Kit

This item is intended for patients who have been prescribed

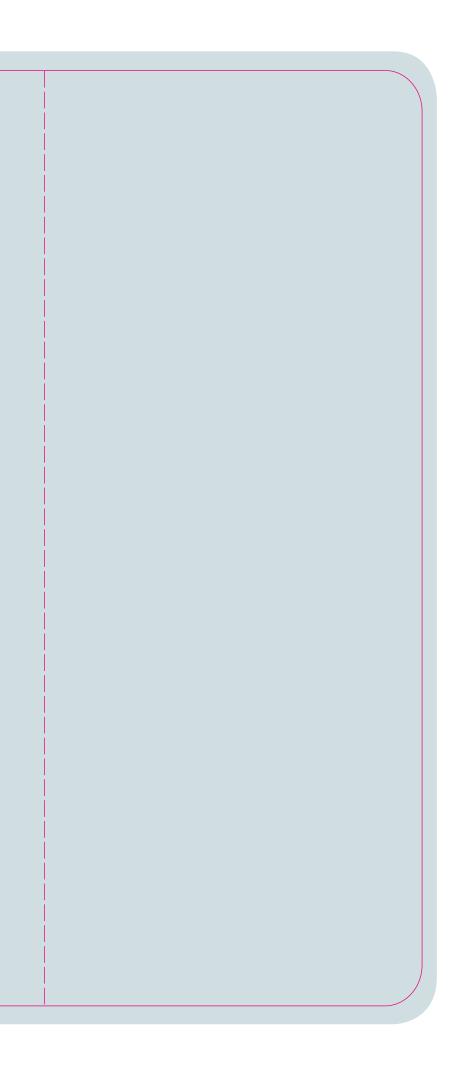
Nucala for injection at home. For full information, please refer to the Consumer Medicine Information that accompanied the Nucala carton.



Scan this QR code with your phone camera to be taken directly to an instruction video, covering step by step instructions on how to use Nucala Pre-filled pen.

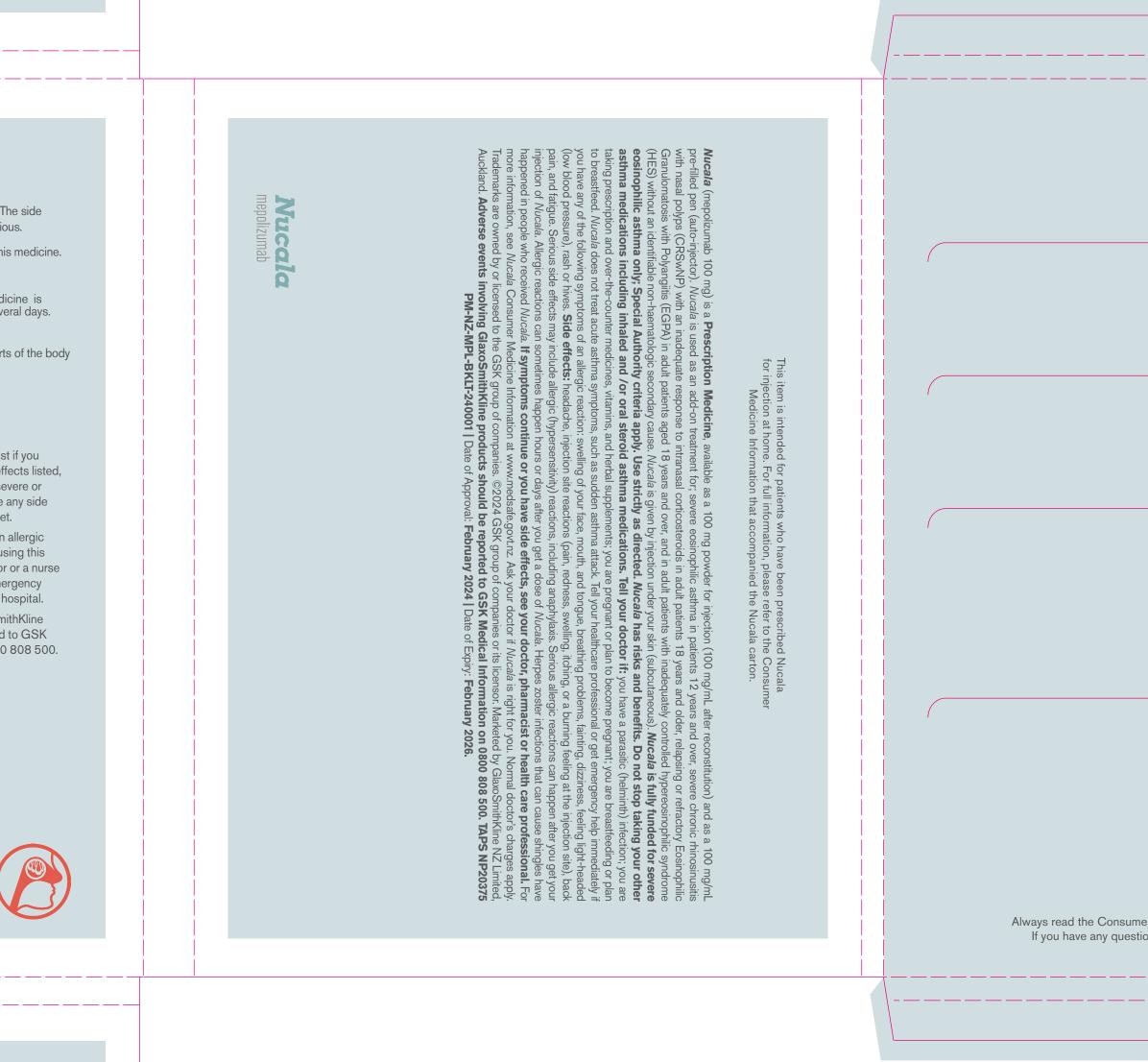
Always read the Consumer Medicine Information before taking this medicine. If you have any questions, speak to your doctor, nurse or pharmacist.

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GSX	©2024 GSK group of companies or its licensor. Trademarks are owned by or licensed to the GSK group of companies. TAPS NP20375 PM-NZ-MPL-BKLT-240001   Date of Approval: February 2024   Date of Expiry: February 20 <b>Nuccala</b> Mepolizumab	126.

**Nucala** mepolizumab



## This patient starter kit

contains what you need to get started with Nucala at home. Included you'll find:

• An introductory booklet

• Instructions for Use

• Frequently asked questions

Link to www.nucala.co.nz/np Where you can find more information on chronic rhinosinusitis with nasal polyps and Nucala

Always read the Consumer Medicine Information before taking this medicine. If you have any questions speak to your Doctor, Nurse or Pharmacist.

## Common questions

#### **O** Is the injection painful?

It might hurt a little. It is recommended to let the Nucala pen come to room temperature for 30 minutes before your injection.

Should I change my injection site every month?

You can inject Nucala into your thigh or abdomen. If someone else gives you the injection, they can also use your upper arm.

#### What happens if I lift the pen before the second click, the stopper has stopped moving, or the inspection window is not filled with the yellow indicator?

If this happens, you may not have received your full dose. For more information, contact GSK at 0800 808 500.

#### What happens if I miss a dose of Nucala?

You or your caregiver 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 your Nucala pen has been out of the refrigerator for more than 7 days, you should throw it away. If you are not sure what to do, ask your doctor, nurse or pharmacist.

## We're here for you along the way

Self-injecting becomes easy with a bit of practice and patience – and sometimes a bit of support. We can help guide you.



## Contact GSK for more information at 0800 808 500 if any of the below occur:

- carton is broken
- If the security seal on the If the medicine is cloudy or discoloured, or has particles
- If the pen looks damaged
  If you need help with your injection

## We're here to help you

## 

Scan this QR code with your phone camera to be taken directly to an instruction video, covering step by step instructions on how to use Nucala Pre-filled pen.

**Nucala** (mepolizumab)

## Instructions for use of your pre-filled pen

This item is intended for patients who have been prescribed Nucala in the pre-filled pen. For full information, please refer to the Consumer Medicine Information that accompanied the Nucala carton.

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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## Let's review the proper way to store your pen

- 30 minutes before use
- Keep it in the carton to protect it from light
- Don't freeze or shake it
- Keep it away from heat
- Keep it refrigerated until
  If needed, you can keep the unopened carton out of the refrigerator, at no more than 30°C, for up to 7 days
  - Keep it out of the reach and sight of children

## Things to remember

**Do not** use the pen more than **Do not** share the pen with once. Throw away the pen other people. according to local requirements after your injection.

dropped or looks damaged. has passed.

**Do not** use the pen if it was **Do not** use if the expiry date

#### Keep Nucala and all medicines out of the reach of children.



Before you start, have the following ready:

An alcohol swab

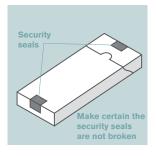


• A cotton ball or gauze 📿

If you don't have these, don't inject. If you have questions, speak to your doctor, nurse or pharmacist.



### 1. Take out your pre-filled pen



Take the

of children.

pre-filled pen out of the tray

Place the pen on a clean,

flat surface, away from direct

sunlight and out of the reach

**Do not** remove the clear

needle cap at this stage.



- Remove the tray from the carton.
- Peel the film cover from the tray.
- **Do not** use the pen if the security seal on the carton is broken.
- Hold on to the middle of the pen and carefully take it out of the tray.

## 2. Inspect and allow to reach room temperature

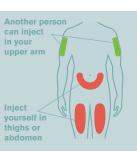


- Check the expirv date on the label of the pen.
- Do not use if the expiry date has passed.
- Look in the inspection window to check that the liquid is clear (free from cloudiness or particles) and colourless or pale yellow to pale brown.
- It is normal to see one or more air bubbles
- Wait 30 minutes (and no more than 8 hours) before use.



- Do not warm your pen 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 pen if it has been left out of the carton for more than 8 hours.
- **Do not** remove the clear 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

**Do not** inject where your

skin is bruised, tender,

Do not inject within

5 cm of your navel

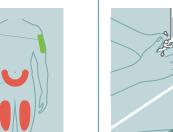
(belly button).

red or hard.

use your upper arm.

4. Clean your injection site

Wash hand



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

**Do not** touch your injection site again until you have completed your injection.

## 2 Inject







- Remove the clear needle cap from the pen by pulling it straight off.
- Do not worry if you see a drop of medicine at the end of the needle. This is normal.
- Inject immediately 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.
- **Do not** put the needle cap back onto the pen. as it may accidentally start the injection.



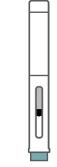


- Hold the pen with its inspection window facing towards you, so you can see it, and with the yellow needle guard facing down.
- Place the pen straight onto your injection site with the yellow needle guard flat on the surface of your skin, as shown.
- To start your injection, push the pen all the way down and keep it held down against your skin. This will make the yellow needle guard slide up into the pen.
- You should hear the first "click" to tell vou vour 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 step, as that may mean you won'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 8) and start again with a new pen.



## 7. Hold the pen in place to complete your injection

ontinue to

hold down

**Do not** lift the pen until

you are certain you have

completed your injection.

You may notice a small

is normal. Press a cotton

ball or gauze on the area

drop of blood at the

injection site. This

for a few minutes

if necessary

Do not rub vour

injection site.

Do not put the

clear needle cap

back onto the pen.

as you

then lift



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

## 8. 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 Sharps bin out of the reach of children.

## What possible side effects might I get?

Like all medication, 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.

Do not use NUCALA if you are allergic to mepolizumab or any of the other ingredients of this medicine.

#### Allergic reactions

Allergic or allergic-like events often occur within minutes to hours after the medicine is administered, but in some instances symptoms can have a delayed onset of up to several days. Some of the symptoms of an allergic reaction may include:

Chest tightness, cough, wheezing or difficulty breathing Drop in blood pressure (fainting, dizziness, feeling lightheaded)

Swelling of the face, lips, tongue or other

parts of the body

#### Other side effects include:

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

• Headache

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

- Injection-site reaction (pain, redness, swelling, itching, and burning sensation of the skin near where the injection was given)
- Eczema (itchy red patches on the skin)
- Back pain
- Pharyngitis (sore throat)
- Lower respiratory tract infection (congestion, cough, discomfort)

Nasal congestion (stuffy nose)

Stomach pain or discomfort

o Vomiting

- Upper abdominal pain (stomach pain or discomfort in the upper area of the stomach)
- Urinary tract infection (blood in urine, painful and
- frequent urination, fever, pain in lower back)

Rash, itching, hives or redness on the skin

Fever (high temperature).

You can help by reporting any side effects you may get. Adverse event with GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500.

#### Registered uses and safety information



Nucala (mepolizumab 100 mg) is a Prescription Medicine, emergency help immediately if you have any of the following available as a 100 mg powder for injection (100 mg/mL symptoms of an allergic reaction: swelling of your face, after reconstitution) and as a 100 mg/mL pre-filled pen mouth, and tongue, breathing problems, fainting, dizziness, (auto-injector). Nucala is used as an add-on treatment for; feeling light-headed (low blood pressure), rash or hives. Side severe eosinophilic asthma in patients 12 years and over, effects: headache, injection site reactions (pain, redness, severe chronic rhinosinusitis with nasal polyps (CRSwNP) swelling, itching, or a burning feeling at the injection site), back with an inadequate response to intranasal corticosteroids pain, and fatigue. Serious side effects may include allergic in adult patients 18 years and older, relapsing or refractory (hypersensitivity) reactions, including anaphylaxis. Serious Eosinophilic Granulomatosis with Polyangiitis (EGPA) in adult allergic reactions can happen after you get your injection of patients aged 18 years and over, and in adult patients with Nucala. Allergic reactions can sometimes happen hours or inadequately controlled hypereosinophilic syndrome (HES) days after you get a dose of Nucala. Herpes zoster infections without an identifiable non-haematologic secondary cause. that can cause shingles have happened in people who Nucala is given by injection under your skin (subcutaneous). received Nucala. If symptoms continue or you have side Nucala is fully funded for severe eosinophilic asthma effects, see your doctor, pharmacist or health care only; Special Authority criteria apply. Use strictly as professional. For more information, see Nucala Consumer directed. Nucala has risks and benefits. Do not stop Medicine Information at www.medsafe.govt.nz. Ask your taking vour other asthma medications including doctor if Nucala is right for you. Normal doctor's charges apply. inhaled and /or oral steroid asthma medications. Tell Trademarks are owned by or licensed to the GSK group of your doctor if: you have a parasitic (helminth) infection; companies. ©2024 GSK group of companies or its licensor. you are taking prescription and over-the-counter medicines, Marketed by GlaxoSmithKline NZ Limited, Auckland. Adverse vitamins, and herbal supplements; you are pregnant or plan to events involving GlaxoSmithKline products should become pregnant: you are breastfeeding or plan to breastfeed. be reported to GSK Medical Information on 0800 808 Nucala does not treat acute asthma symptoms, such as 500. TAPS NP20375 PM-NZ-MPL-BKLT-240001 Date of sudden asthma attack. Tell your healthcare professional or get Approval: February 2024 | Date of Expiry: February 2026.

GSK

Nucala (mepolizumab) Frequently asked questions

This booklet is intended for use by patients prescribed Nucala for injection at home. For full information, please refer to the Consumer Medicine Information that accompanied the Nucala carton.

Adverse events should also be reported to GlaxoSmithKline on 0800 808 500.

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

I've found out I have chronic hinosinusitis with nasal polyps. Vhat does this mean?

**.** 

Eosinophils are a type of white blood cell. They help to defend your body against infections.

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Eosinophils, along with other cell types, also contribute to inflammation that can lead to the development of nasal polyps when they accumulate in your nasal passages. These eosinophils can cause our airways to become inflamed, potentiall creating an environment where nasal polyps can grow.

### What is Nucala and how does it work?

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Nucala (mepolizumab) is a biologic medicine specifically designed to treat CRSwNP. It's an injection that you take once every 4 weeks – either at home or at your doctor's office – in addition to your current CRSwNP medications.



Nucala works by lowering the number of eosinophils in your blood, which decreases the airway inflammation that may contribute to your nasal polyps and their symptoms.

I've been prescribed Nucala to take at home. How often should I use it?

You need to take Nucala every 4 weeks as prescribed by your doctor, even if you're feeling better. Nucala is taken in addition to your other CRSwNP medications.

It may be easier to remember to take Nucala every 4 weeks if you make it part of your routine. Keep track of your injections by writing down the day in a calendar.

How should I store my Nucala at home?

Until you need it, keep your Nucala in its original carton, in your refrigerator and out of the light. Nucala should be stored between 2°C and 8°C. Unopened cartons can be stored at up to 30°C, for up to 7 days (again, out of the light).

A few important things to remember: do not freeze or shake your Nucala, and keep it away from heat.

Safely dispose of any Nucala that is out of date, no longer needed or has been outside its carton for more than 8 hours, or has been out of the refrigerator for more than 7 days. Speak to your pharmacist if you have any questions about this.

#### How do I use my Nucala at home?

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Please follow the instructions provided in the carton with your medicine. Detailed instructions on preparing your Nucala and your injection site, as well as instructions for self-injecting, can also be found in the "Instructions for Use" leaflet that accompanied this kit. If you have any questions, please ask your doctor.

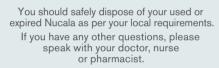
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How do I safely dispose of my Nucala?

You should safely dispose of your used or expired Nucala as per your local requirements.

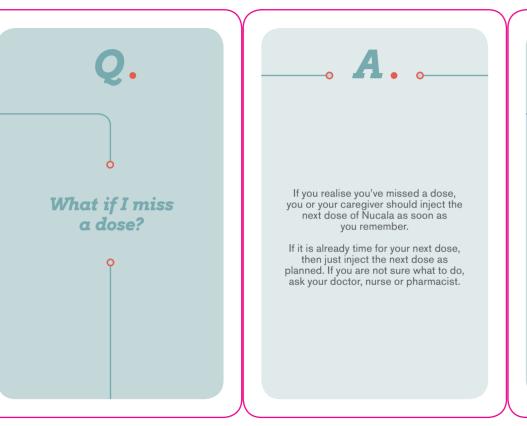
Ask your doctor or pharmacist for advice if necessary.







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### How do I travel with my Nucala

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When traveling, keep Nucala in the original packaging and protected from light. You may keep it at room temperature. up to 30°C, for no more than 7 days when kept in the original carton.

If you do take your medicine out of its carton, it should be used within 8 hours. Throw the Nucala away if it has been kept out of the refrigerator for more than 7 days.

How well will Nucala work?

As with any medication, the response to Nucala differs from person to person. Some patients taking Nucala have reduced nasal polyp size or reduced nasal obstruction: others have improved sense of smell or need less steroids (although not all patients saw improvements). Any improvements you may see might take a bit of time, so it's a good idea to kee track of your CRSwNP-related symptom

The monthly tracker provided in this kit will help you do this and it is useful to bring it with you to your specialist appointments, so that any progress you make can be monitored.

Nucala can only have an effect if you keep taking it, so you need to keep taking Nucala regularly - even i vou feel better.

What possible side effects m

I experience

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Like all medications, Nucala can cause side effects. The side effects caused by Nucala are usually mild to moderate bu can occasionally be serious.

#### Allergic reactions

Some people may have allergic or allergic-like reactions. They usually occur within minutes to hours after the injection, but sometimes symptoms car 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 the face, lips, tongue or other parts of the body

Hives

Rash

#### Other side effects include:

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

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

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- Eczema (itchy red patches on the skin)
- Back pain
- Pharyngitis (sore throat)
- Lower respiratory tract infection (congestio) cough. discomfort)
- Nasal congestion (stuffy nose)
- Upper abdominal pain (stomach pain or discomfort in the upper area of the stomach)
- Urinary tract infection (blood in urine, painful and frequent urination, fever, pain in lower
- Fever (high temperature)



Rare side effects (up to 1 in 1,000 people):

Severe allergic reactions (anaphylaxis)

Tell your doctor or pharmacist if you experience any of the side effects listed, particularly if they become severe or troublesome, or if you notice any side effects not listed in this leaflet.

If you think you are having an allergic reaction to NUCALA, stop using this medicine and tell your doctor or a nurse immediately or go to the Emergency Department at your nearest hospital.

Can I take Nucala if I am pregnant

Tell your doctor if you are pregnant or plan to become pregnant. The effect of Nucala on human pregnancy is unknown. Nucala should be used during pregnancy only if the expected benefit to the mother justifies the potential risk to the foetus. Talk with your doctor for more information about Nucala and pregnancy.

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Where can I receiv further support? \_\_\_\_o **\_\_\_** • o\_\_\_

The following websites may be

useful for additional information

NUCALA PATIENT WEBSIT

www.nucala.co.nz/np

HEALTH NAVIGATOR NZ

www.healthnavigator.org.nz

Nucala (mepolizumab 100 mg) is a Prescription Medicine, available a 100 mg powder for injection (100 mg/mL after reconstitution) a a 100 mg/mL pre-filled pen (auto-injector). Nucala is used as an dd-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 / years and older, relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA) in adult patients aged 18 years and over, and in adu patients with inadequately controlled hypereosinophilic syndrome (HES vithout an identifiable non-haematologic secondary cause. Nucala en by injection under your skin (subcutaneous). Nucala is full funded for severe eosinophilic asthma 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; y re taking prescription and over-the-counter medicines, vitamins, and rbal supplements: you are pregnant or plan to become pregnant; yo e 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 t 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 th 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 ha happened in people who received Nucala. If symptoms continue of 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 Nuca is right for you. Normal doctor's charges apply. Trademarks are owne by or licensed to the GSK group of companies. ©2024 GSK grou of companies or its licensor. Marketed by GlaxoSmithKline NZ Limited ckland. Adverse events involving GlaxoSmithKline product should be reported to GSK Medical Information on 0800 808 500. TAPS NP20375 PM-NZ-MPL-BKLT-240001 Date of Approva February 2024 Date of Expiry: February 2026.