READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrNUCALA
[new-ka′ la]

Mepolizumab for Injection

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) is a prescription medicine used in addition to other asthma medicines to treat adult patients 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.

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, sinonasal symptoms, and breathlessness.

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.

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 sucrose, sodium phosphate dibasic heptahydrate, and polysorbate 80.

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 or Eosinophilic Granulomatosis with Polyangiitis. **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.

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.

- If you have not had chickenpox (varicella) or chickenpox 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. There is a pregnancy registry for women who receive NUCALA while pregnant. The purpose of the registry is to collect information about the health of you and your baby. You can talk to your healthcare provider about how to take part in this registry or you can get more information and register by calling 1-877-311-8972 or go to http://mothertobaby.org/asthma/.

- 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 and adolescents under 18 years old.

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 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
The recommended dose of NUCALA for severe eosinophilic asthma 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 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:

In case of drug overdose, contact your 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?

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.

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.

Allergic or Allergic-like reactions
Some people may have allergic or allergic-like reactions. 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 may be having a reaction.

If you 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: -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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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 package to protect from light.
- Store at room temperature (below 25ºC). 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 Health Canada website; 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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