

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

Pr NUCALA™
[new-ka' la]

mepolizumab lyophilized powder for subcutaneous 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?

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 other problems caused by eosinophils. NUCALA™ is not used to treat acute asthma symptoms, such as a sudden asthma attack.

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 and lungs.

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 take NUCALA™ if:

- you are **allergic** to mepolizumab or any of the other ingredients of this medicine. **Check with your doctor** if this may apply to you.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take 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 get worse while receiving injections of NUCALA™.
- Tell your doctor if you are taking corticosteroids for the treatment of asthma. **Do not suddenly stop taking** your corticosteroids 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, talk to your doctor before using NUCALA™, as 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 have a baby, **ask your doctor for advice** 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 breast-feeding or plan to breast-feed, you must check with 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.

The possible side effects of NUCALA™ are unlikely to affect your ability to drive and use machines.

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, such as a doctor or nurse.

Usual dose:

The recommended dose of NUCALA™ is 100 mg, given as 1 injection under the skin (subcutaneous) every four weeks.

Do not stop receiving injections of NUCALA™ unless your doctor advises you to. Interrupting or stopping the treatment with NUCALA™ may cause your asthma symptoms and attacks to come back or occur more frequently. If your asthma symptoms get worse while receiving injections of NUCALA™, call 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 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:

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

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

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

- Headache

Common side effects

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

- Injection-site reaction (pain, erythema, swelling, itching, and burning sensation of the skin near where the injection was given)
- Back pain
- Sore throat (pharyngitis)
- Congestion, cough, discomfort (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)

Tell your healthcare professional immediately if you get any of these symptoms, or if you notice any side effects not listed in this leaflet.

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 0K9Postage 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 which is stated on the label. The expiry date refers to the last day of that month. Store in the original carton at room temperature (below 25°C) until use. Do not freeze. Protect from light.

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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