PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE

PHARMACIST'S REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Nucala

Powder for solution for injection

Each vial contains 100 mg mepolizumab (100 mg/ml after reconstitution).

Inactive and allergenic ingredients in the preparation – see section 6 "Additional information" and section 2 "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is used for treatment of:

→ Adult patients with **severe eosinophilic asthma**, which is not responding to other treatments, in combination with other medicines.

→ Adult patients with **Eosinophilic Granulomatosis with Polyangiitis (EGPA)** - Churg-Strauss Disease.

Therapeutic group

Monoclonal antibody.

Nucala contains the active ingredient **mepolizumab**, *a monoclonal antibody*, a type of protein designed to recognize a specific target substance in the body.

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 which Nucala can treat.

If you are already being treated with medicines such as high-dose inhalers, but your asthma is not well controlled, Nucala can reduce the number of asthma attacks.

If you are taking *oral corticosteroids*, Nucala can also help reduce the daily dosage needed to control your ailment.

Mepolizumab, the active ingredient in Nucala, blocks a protein called interleukin-5. Blocking the activity of this protein reduces the production of eosinophils in the bone marrow, and lowers the number of eosinophils in the bloodstream and the lungs.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (**allergic**) to the active ingredient (mepolizumab) or to any of the additional ingredients contained in the medicine (detailed in section 6).

Special warnings regarding use of the medicine

Asthma exacerbation

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

→ **Tell your physician or nurse** if your asthma remains uncontrolled, or worsens, after starting Nucala treatment.

Allergic and injection-site reactions

Medicines of this type *(monoclonal antibodies*) can cause severe allergic reactions when injected (see section 4, "Side effects").

If you have experienced a similar reaction to any type of injection or medicine,

→ **Tell your physician before receiving 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 such infections are common or if you are travelling to such a region:

→ **Check with your physician.**

Children and adolescents

This medicine is not intended for use **in children or adolescents under the age of 18.**

Drug interactions

If you are taking, or have recently taken, or are about to take other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist, especially if you are taking:

Other medicines for treating asthma or eosinophilic granulomatosis with polyangiitis.

Consult your physician before discontinuing other prophylactic medicines for treatment of your ailment, once starting treatment with Nucala. You should stop taking these medicines gradually (especially medicines called *corticosteroids*) *per your physician's instructions only,* under the direct supervision of your physician and depending on your

response to Nucala.

Pregnancy and breast-feeding

If you are pregnant, if you think you are pregnant or are planning to become pregnant, **consult your physician** before using the medicine.

It is not known whether the ingredients of Nucala can pass into breast milk. **If you are breast-feeding, consult your physician** before using Nucala.

Driving and using machines

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

Important information about some of the ingredients of the medicine

Nucala contains sodium

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. You should check with the physician or the pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

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

The dosage and treatment regimen will be determined only by the physician.

The recommended dosage is generally:

For treatment of severe eosinophilic asthma - 100 mg, one injection every four weeks.

Eosinophilic granulomatosis with polyangiitis - 300 mg (three 100 mg injections), once every four weeks.

Do not exceed the recommended dose.

If you missed a dose of Nucala, contact your physician or hospital as soon as possible to re-schedule your appointment.

Adhere to the treatment as recommended by the physician.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

Do not stop receiving injections of Nucala unless so advised by your physician.

Stopping or interrupting treatment with Nucala may cause symptoms and attacks of your ailment to return.

If the symptoms of your ailment worsen while receiving injections of Nucala

→ **Call your physician.**

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Nucala may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Allergic reactions

Some people may suffer from allergic or allergic-like reactions. These reactions may be common (may affect **up to 1 in 10 people**). They usually occur within minutes to hours after the injection, but sometimes symptoms may appear 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 eyelids, face, lips, tongue or mouth
- Hives
- Rash

→ **Seek medical help immediately** if you think you may be suffering from an allergic reaction.

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

→ Tell your physician before you receive Nucala.

Other side effects

Very common side effects

Occur **in more than 1 in 10 people:**

- Headache

Common side effects

Occur **in up to 1 in 10 people:**

- Chest infection - symptoms may include cough and fever (high temperature)
- Urinary tract infection (blood in the urine, painful urination and increase in the frequency of urination, fever, pain in lower back)

- Upper abdominal pain (stomach pain or discomfort in the upper part of the stomach)
- High fever
- Itching (eczema - red and itchy patches on the skin)
- Injection-site reactions (pain, redness, swelling, itching, and burning sensation of the skin in the area near the injection site)
- Back pain
- Pharyngitis (sore throat)
- Nasal congestion (stuffy nose)

Rare side effects

Occur **in up to 1 in 1,000 people:**

- Severe allergic reactions (anaphylaxis)

→ **Refer immediately to your physician or to a nurse** if you develop any of these symptoms.

If a side effect occurred, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician, pharmacist or nurse.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not freeze.
- Store in the original package in order to protect from light.

6. ADDITIONAL INFORMATION

- **In addition to the active ingredient, the medicine also contains -**

Sucrose, sodium phosphate dibasic heptahydrate, polysorbate 80, hydrochloric acid, water for injection.

- **What the medicine looks like and the content of the package**

Nucala is supplied as a white powder, in a clear colorless glass vial with a rubber stopper.

Nucala is available in a pack containing one vial or in a pack containing 3 vials.

Not all pack sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Manufacturing S.p.A., Parma, Italy.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 157-57-34861-00.

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Nuc PT v3A