

PATIENT INFORMATION
RELEUKO® (reh-loo-koe)
(filgrastim-ayow)
injection

What is RELEUKO?

RELEUKO is a man-made form of granulocyte colony-stimulating factor (G-CSF). G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection.

Do not take RELEUKO if you have had a serious allergic reaction to human G-CSFs such as filgrastim products or pegfilgrastim products.

Before you take RELEUKO, tell your healthcare provider about all of your medical conditions, including if you:

- have a sickle cell disorder.
- have kidney problems.
- are receiving radiation therapy.
- are pregnant or plan to become pregnant. It is not known if RELEUKO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if RELEUKO passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive RELEUKO?

- **RELEUKO injections can be given by a healthcare provider by intravenous (IV) infusion or under your skin (subcutaneous injection). Your healthcare provider may decide subcutaneous injections can be given at home by you or your caregiver. If RELEUKO is given at home, see the detailed "Instructions for Use" that comes with your RELEUKO for information on how to prepare and inject a dose of RELEUKO.**
- You and your caregiver should be shown how to prepare and inject RELEUKO before you use it, by your healthcare provider.
- You should not try to inject a dose of RELEUKO less than 0.3 mL (180 mcg) from a RELEUKO prefilled syringe. A dose less than 0.3 mL cannot be accurately measured using the RELEUKO prefilled syringe.
- Your healthcare provider will tell you how much RELEUKO to inject and when to inject it. Do not change your dose or stop RELEUKO unless your healthcare provider tells you to.
- If you are receiving RELEUKO because you are also receiving chemotherapy, your dose of RELEUKO should be injected **at least 24 hours before** or **24 hours after** your dose of chemotherapy. Your healthcare provider will do blood tests to monitor your white blood cell count, and if necessary, adjust your RELEUKO dose.
- If you miss a dose of RELEUKO, talk to your healthcare provider about when you should give your next dose.

What are the possible side effects of RELEUKO?

RELEUKO may cause serious side effects, including:

- **Spleen rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Call your healthcare provider right away if you have pain in the left upper stomach (abdomen) area or your left shoulder.
- **A serious lung problem called acute respiratory distress syndrome (ARDS).** Call your healthcare provider or get emergency medical help right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- **Serious allergic reactions.** RELEUKO can cause serious allergic reactions. These reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate, and sweating. If you have any of these symptoms, stop using RELEUKO and call your healthcare provider or get emergency medical help right away.
- **Sickle cell crises.** You may have a serious sickle cell crisis, which could lead to death, if you have a sickle cell disorder and receive RELEUKO. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** RELEUKO can cause kidney injury. Call your healthcare provider right away if you develop any of the following symptoms:
 - swelling of your face or ankles
 - blood in your urine or dark colored urine
 - you urinate less than usual
- **Capillary leak syndrome.** RELEUKO can cause fluid to leak from blood vessels into your body's tissues. This condition is called "Capillary Leak Syndrome" (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
 - swelling or puffiness and are urinating less than usual
 - trouble breathing
 - swelling of your stomach area (abdomen) and feeling of fullness
 - dizziness or feeling faint

- a general feeling of tiredness
- **Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML).**
 - RELEUKO may increase the risk of developing a precancerous condition called MDS or a type of blood cancer called AML in people who were born with low white blood cell counts (congenital neutropenia).
 - If you have breast cancer or lung cancer, when RELEUKO is used with chemotherapy and radiation therapy, or with radiation therapy only, you may have an increased risk of developing MDS or AML.
 - Symptoms of MDS and AML may include tiredness, fever, and easy bruising or bleeding.
 - Call your healthcare provider if you develop any of these symptoms during treatment with RELEUKO.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with RELEUKO. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with RELEUKO. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood during treatment with RELEUKO.
- **Inflammation of your blood vessels (cutaneous vasculitis).** Tell your healthcare provider right away if you develop purple spots or redness of your skin.
- **Inflammation of the aorta (aortitis).** Inflammation of the aorta (the large blood vessel which transports blood from the heart to the body) has been reported in patients who received filgrastim products. Symptoms may include fever, abdominal pain, feeling tired, and back pain. Call your healthcare provider if you experience these symptoms.

The most common side effects experienced in patients receiving RELEUKO include:

- Patients with cancer receiving chemotherapy: fever, pain, rash, cough, and shortness of breath
- Patients with acute myeloid leukemia receiving chemotherapy: pain, nose bleed, and rash
- Patients with cancer receiving chemotherapy followed by bone marrow transplant: rash
- Patients with severe chronic neutropenia: pain, decreased red blood cells, nose bleed, diarrhea, reduced sensation, and hair loss

These are not all the possible side effects of RELEUKO. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RELEUKO?

- Store RELEUKO in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.
- Keep RELEUKO in the original pack to protect from light or physical damage. Do not leave RELEUKO in direct sunlight.
- **Do not** shake RELEUKO.
- Take RELEUKO out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any RELEUKO that has been left at room temperature for longer than 24 hours.
- After you inject your dose, throw away (dispose of) any unused RELEUKO left in the vials or prefilled syringes. **Do not** save unused RELEUKO in the vials or prefilled syringes for later use.

Keep RELEUKO and all medicines out of the reach of children.

General information about the safe and effective use of RELEUKO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use RELEUKO for a condition for which it was not prescribed. Do not give RELEUKO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about RELEUKO that is written for healthcare professionals.

What are the ingredients in RELEUKO?

Active ingredient: filgrastim-ayow

Inactive ingredients: acetic acid, polysorbate 80, sodium hydroxide, sorbitol and water for injection

Manufactured by: **Kashiv BioSciences, LLC**, Piscataway, NJ 08854

US License No. 2131

Distributed by: **Amneal Pharmaceuticals LLC**, Bridgewater, NJ 08807

For more information go to www.Releuko.us or call 1-877-835-5472.