

Questions to ask your doctor

Talking about white blood cell counts and risk of infection

The questions below can help you start a discussion with your doctor about your white blood cell counts, the risk of infection, and how NEUPOGEN[®] may be able to help.

- ◆ What are blood counts?
- ◆ Am I at risk for neutropenia and infection?
- ◆ Why does some chemotherapy increase my risk of infection?
- ◆ What effect can a low white blood cell count or an infection have on me?
- ◆ How can the risk of complications from febrile neutropenia be minimized?
- ◆ What is NEUPOGEN[®]?
- ◆ Do I need NEUPOGEN[®]?
- ◆ What are the side effects associated with NEUPOGEN[®]?
- ◆ What else can I do to help protect against infection?
- ◆ What other resources offer information and support for patients on chemotherapy?

NEUPOGEN[®] is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (non-myeloid) who receive anti-cancer medicines (chemotherapy) that can cause fever and a low blood cell count.

Please see Important Safety Information on the next page.

Important Safety Information

Do not take NEUPOGEN[®] if you have had a serious allergic reaction to human G-CSFs such as (filgrastim) or (pegfilgrastim) products.

Before you take NEUPOGEN[®], tell your healthcare provider all about your medical conditions, including if you:

- have a sickle cell disorder.
- have kidney problems.
- are receiving radiation therapy.
- are allergic to latex. The needle cap on the prefilled syringe contains dry natural rubber (derived from latex). You should not give NEUPOGEN[®] using the prefilled syringe if you have latex allergies. Ask your healthcare provider about using the vial if you have latex allergies.
- are pregnant, or plan to become pregnant. It is not known if NEUPOGEN[®] will harm your unborn baby.
- are breastfeeding, or plan to breastfeed. It is not known if NEUPOGEN[®] 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 NEUPOGEN[®]?

- NEUPOGEN[®] 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 NEUPOGEN[®] is given at home, see the detailed "Instructions for Use" that comes with your NEUPOGEN[®] for information on how to prepare and inject a dose of NEUPOGEN[®].
- You and your caregiver should be shown how to prepare and inject NEUPOGEN[®] before you use it, by your healthcare provider.
- Your healthcare provider will tell you how much NEUPOGEN[®] to inject and when to inject it. Do not change your dose or stop NEUPOGEN[®] unless your healthcare provider tells you to.
- If you are receiving NEUPOGEN[®] because you are also receiving chemotherapy, your dose of NEUPOGEN[®] 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 NEUPOGEN[®] dose.
- If you are receiving NEUPOGEN[®] because you have been suddenly (acutely) exposed to an amount of radiation that can affect your bone marrow (Acute Radiation Syndrome), you will need to have blood tests about every 3 days during treatment with NEUPOGEN[®] to check your white blood cell count.
- If you miss a dose of NEUPOGEN[®], talk to your healthcare provider about when you should be given your next dose.

What are possible side effects of NEUPOGEN[®]?

NEUPOGEN[®] 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 area or 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.** NEUPOGEN[®] 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 NEUPOGEN[®], and call your healthcare provider or get emergency 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 NEUPOGEN[®]. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** NEUPOGEN[®] can cause kidney injury. Call your healthcare provider right away if you develop any of the following symptoms:
 - o swelling of your face and ankles
 - o blood in your urine or dark colored urine
 - o you urinate less than usual
- **Capillary Leak Syndrome.** NEUPOGEN[®] 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:
 - o swelling or puffiness and are urinating less than usual
 - o trouble breathing
 - o swelling of your stomach-area and feeling of fullness
 - o dizziness or feeling faint
 - o a general feeling of tiredness
- **Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML).** NEUPOGEN[®] 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 NEUPOGEN[®] 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 NEUPOGEN[®].
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with NEUPOGEN[®]. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with NEUPOGEN[®]. 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 NEUPOGEN[®].
- **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 NEUPOGEN[®]. 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 NEUPOGEN[®]:

- 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 who are having their own blood cells collected: bone pain, fever, and headache
- 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 effect of NEUPOGEN[®]. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-332-1088.

Please see the NEUPOGEN[®] [Patient Information](#) for additional information.