NEUPOGEN is filgrastim

The **only** G-CSF approved with 5 indications

**IMPORTANT SAFETY INFORMATION**

NEUPOGEN is contraindicated in patients with known hypersensitivity to *E coli*-derived proteins, such as filgrastim, or any component of the product.

Allergic reactions, including anaphylaxis, occurred with initial or subsequent treatment. Some reactions occurred on initial exposure. Reactions tended to occur within the first 30 minutes after administration and appeared to occur more frequently in patients receiving NEUPOGEN IV.

Please see additional Important Safety Information on back cover.
NEUPOGEN: the only daily G-CSF with 5 indications

**Indication**

**Duration of administration**

**Recommended dosing and administration**

**Patients with cancer receiving myelosuppressive chemotherapy**

To decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs, associated with a significant incidence of severe neutropenia with fever. A complete blood count and platelet count should be obtained prior to chemotherapy, and twice a week during NEUPOGEN therapy to avoid leukocytosis and to monitor the neutrophil count.

Up to 3 weeks, until the ANC has reached 10,000/mm³ following the expected chemotherapy-induced neutrophil nadir. Discontinue NEUPOGEN if the ANC surpasses 10,000/mm³ after the expected nadir.

Starting dose of 5 mcg/kg/day administered as single daily injection by subcutaneous (SC) bolus, short IV infusion, or continuous SC or IV infusion. Administer no earlier than 24 hours after cytotoxic chemotherapy, and daily for up to 2 weeks until ANC has reached 10,000/mm³ following expected chemotherapy-induced neutrophil nadir. Discontinue if ANC surpasses 10,000/mm³ after expected nadir.

**Patients with acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy**

For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

20 days (median)

In a clinical trial, patients with AML receiving induction or consolidation chemotherapy, received NEUPOGEN at 5 mcg/kg/day SC, from 24 hours after the last dose of chemotherapy until neutrophil recovery or for up to 35 days. NEUPOGEN was dosed until neutrophil levels reached an ANC of 1,000/mm³ for 3 consecutive days or to an ANC of 10,000/mm³ for 1 day.

**Patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy**

For the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Recommended to be given for at least 4 days before the first leukapheresis procedure and continued until the last leukapheresis, generally 6-7 days. Monitor neutrophils after 4 days of NEUPOGEN.

Administer NEUPOGEN at 10 mcg/kg/day SC as a bolus or continuous infusion for at least 4 days before first leukapheresis procedure and continued until the last leukapheresis for mobilization of PBPC.

**Patients with cancer receiving bone marrow transplant**

To reduce the duration of neutropenia and neutropenia-related clinical sequelae eg, febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation.

Titrate dose based on ANC, reduce to 5 mcg/kg/day if ANC > 1,000/mm³ for 3 consecutive days, if ANC remains > 1,000/mm³ for 3 more consecutive days discontinue NEUPOGEN, then if ANC < 1,000/mm³ resume at 5 mcg/kg/day.

Recommended dose is 10 mcg/kg/day administered as an IV infusion of 4 or 24 hours, or as continuous 24-hour SC infusion. First dose should be administered at least 24 hours after cytotoxic chemotherapy and administered at least 24 hours after bone marrow infusion.

Titration may be necessary based on neutrophil recovery. Please see the NEUPOGEN prescribing information for detailed titration information.

**Patients with severe chronic neutropenia (SCN)**

For chronic administration to reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

It is essential that serial CBCs with differential and platelet counts and an evaluation of bone marrow morphology and karyotype be performed prior to initiation of NEUPOGEN therapy. The use of NEUPOGEN prior to confirmation of SCN may impair diagnostic efforts and may thus impair or delay evaluation and treatment of an underlying condition, other than SCN, causing the neutropenia.

Daily administration. Note: ANC should not be used as the sole indication of efficacy. The dose should be individually adjusted based on the patient’s clinical course as well as ANC.

Starting dose of NEUPOGEN for congenital neutropenia is 6 mcg/kg twice daily SC.

**Initial US approval**


**Years of use**

22 years.

**Structure/pharmacokinetics**

- Human granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology.
- Elimination half-life: approximately 3.5 hours.

**Clearance**

- Primarily renal clearance.

**Dosing**

- Daily injections: Please see adjacent page for indication-specific dosing.
- Available in single-dose syringes and vials.
- Weight-based dosing using 300 mcg or 480 mcg vials.

---

Amgen is committed to helping you and your appropriate patients access G-CSF

**Patient Support Programs**

Patients who need financial assistance may be eligible for help from:
- The Amgen FIRST STEP™ Co-pay Coupon Program, which now provides co-pay assistance for patients receiving NEUPOGEN®
- Independent co-pay foundations
- The Safety Net Foundation®, which provides certain therapies at no cost for eligible patients
- Amgen Assist®, which helps patients identify co-pay foundations

**Biotechnology by Amgen**

Amgen has 30+ years of experience in the research, development, and manufacturing of complex biologic therapies
- Amgen has a track record of reliable supply of high-quality medicines to patients worldwide
- For more information, please visit www.biotechnologybyamgen.com

---

**References:**

4. Years of use
5. Initial US approval
6. NEUPOGEN if the ANC surpasses 10,000/mm³ after expected chemotherapy-induced neutrophil nadir. Discontinue if ANC surpasses 10,000/mm³ after expected nadir.

---

**Please see Important Safety Information on back cover.**
Important Safety Information

NEUPOGEN® (filgrastim) is contraindicated in patients with known hypersensitivity to *E coli*-derived proteins, such as filgrastim, or any component of the product.

Allergic reactions, including anaphylaxis, occurred with initial or subsequent treatment. Some reactions occurred on initial exposure. Reactions tended to occur within the first 30 minutes after administration and appeared to occur more frequently in patients receiving NEUPOGEN IV.

**SPLENIC RUPTURE, INCLUDING FATAL CASES, HAS BEEN REPORTED. IF PATIENTS REPORT LEFT UPPER ABDOMINAL AND/OR SHOULDER TIP PAIN, THEY SHOULD BE EVALUATED FOR AN ENLARGED SPLEEN OR SPLENIC RUPTURE.**

Acute respiratory distress syndrome (ARDS) has been reported. Evaluate patients who develop fever, lung infiltrates, or respiratory distress for ARDS. If patient is diagnosed with ARDS, discontinue and/or withhold NEUPOGEN until resolution.

Alveolar hemorrhage, manifesting as pulmonary infiltrates and hemothysis requiring hospitalization, has been reported in healthy donors undergoing peripheral blood progenitor cell mobilization, an unapproved use of NEUPOGEN. Hemothysis resolved with discontinuation of NEUPOGEN. The use of NEUPOGEN for peripheral blood progenitor cell mobilization in healthy donors is not an approved indication.

Severe sickle cell crises, in some cases resulting in death, have been associated with the use of NEUPOGEN in patients with sickle cell disorders.

Thrombocytopenia has been reported commonly in patients receiving NEUPOGEN. Platelet counts should be monitored closely.

The safety and efficacy of NEUPOGEN in the treatment of neutropenia due to other hematopoietic disorders (eg, myelodysplastic syndrome [MDS]) have not been established.

Cytogenetic abnormalities, transformation to MDS, and acute myeloid leukemia (AML) have been observed in patients treated with NEUPOGEN for severe chronic neutropenia. The risk of developing MDS and AML appears to be confined to the subset of patients with congenital neutropenia. If a patient with severe chronic neutropenia (SCN) develops abnormal cytogenetics or myelodysplasia, the risks and benefits of continuing NEUPOGEN should be carefully considered.

NEUPOGEN is a growth factor that primarily stimulates neutrophils. However, the possibility that NEUPOGEN can act as a growth factor for any tumor type cannot be excluded.

Cutaneous vasculitis has been reported in patients treated with NEUPOGEN. Most cases were moderate or severe and involved patients with SCN receiving long-term NEUPOGEN therapy. Symptoms of vasculitis generally developed simultaneously with an increase in the ANC and abated when the ANC decreased. Many patients were able to continue NEUPOGEN at a reduced dose.

In clinical trials of cancer patients receiving myelosuppressive chemotherapy involving NEUPOGEN, medullary bone pain was the most frequently reported adverse event attributed to NEUPOGEN therapy.

In clinical trials of patients with AML, adverse events reported in ≥ 5% of patients and more frequently in patients receiving NEUPOGEN than placebo included: petechiae, epistaxis, transfusion reactions, and hemorrhagic events (including severe or fatal hemorrhagic events).

In randomized clinical trials of cancer patients receiving bone marrow transplant, the following adverse events were reported in ≥ 5% of patients and more frequently in patients treated with NEUPOGEN than in controls included: nausea, vomiting, hypertension, rash, and peritonitis.

In clinical trials of cancer patients undergoing peripheral blood progenitor cell collection and therapy, adverse events reported in ≥ 5% of patients and related to NEUPOGEN consisted primarily of mild-to-moderate musculoskeletal symptoms. These symptoms were predominantly events of medullary bone pain. Other reported events included headache and transient increases in alkaline phosphatase (reported in patients who had serum chemistries measured), mild to moderate anemia, and decreased platelet counts.

In clinical trials of patients with severe chronic neutropenia, the following were reported in ≥ 5% of patients: mild-to-moderate bone pain, palpable splenomegaly, epistaxis, anemia, and thrombocytopenia.

Please see accompanying package insert for full Prescribing Information.