NEUPOGEN is filgrastim

The **only** G-CSF available in vials and prefilled syringes

Syringes available in single packs.*

Vials and syringes also available in packs of 10.

*Minimum order of 4 single packs.

NEUPOGEN® is administered by subcutaneous (SC) injection or intravenous (IV) infusion.

Indication

NEUPOGEN® is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Please see Important Safety Information on page 4.

NEUPOGEN® (FILGRASTIM)

NEUPOGEN delivers more packaging options

- Single packs, each containing 1 prefilled syringe*[1]

- Multipacks, each containing 10 prefilled syringes[1]

- Multipacks, each containing 10 vials[1]

NEUPOGEN product information

SingleJect® prefilled syringes

Pack quantity	NDC	Description	Bundle quantity
1 syringe SINGLE PACK	55513-924-91	300 mcg/0.5 mL (600 mcg/mL) single-use syringe	4 packs
1 syringe SINGLE PACK	55513-209-91	480 mcg/0.8 mL (600 mcg/mL) single-use syringe	4 packs
10 syringes	55513-924-10	300 mcg/0.5 mL (600 mcg/mL) single-use syringe	N/A
10 syringes	55513-209-10	480 mcg/0.8 mL (600 mcg/mL) single-use syringe	N/A

Vials

10 vials	55513-530-10	300 mcg/1.0 mL (300 mcg/mL) single-use vial	4 packs
10 vials	55513-546-10	480 mcg/1.6 mL (300 mcg/mL) single-use vial	4 packs

*Minimum order of 4 single packs.

Please see Important Safety Information on page 4.

NEUPOGEN® (FILGRASTIM)

Dosing and administration

Starting dosage of 5 mcg/kg/day, administered as a single daily injection by subcutaneous injection, by short intravenous infusion (15 to 30 minutes), or by continuous intravenous infusion. Obtain a CBC and platelet count before instituting therapy and monitor twice weekly during therapy. Consider dose escalation in increments of 5 mcg/kg for each chemotherapy cycle, according to the duration and severity of ANC nadir. Recommend stopping NEUPOGEN if ANC increases > 10,000/mm^3. Administer ≥ 24 hours after cytotoxic chemotherapy; do not administer within the 24-hour period prior to chemotherapy. Administer daily for up to 2 weeks or until the ANC has reached 10,000/mm^3 following the expected chemotherapy-induced neutrophil nadir.

Initial US approval

1991[1]

Years of use

24 years[1]

Structure/pharmacokinetics

- Human granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology[1]
- Elimination half-life: approximately 3.5 hours[1]

Clearance

- Primarily renal clearance[2]

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 commercially insured 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**

BIOTECHNOLOGY BY AMGEN®

Please see Important Safety Information on page 4.

References: 1. NEUPOGEN® (filgrastim) Prescribing Information. Thousand Oaks, CA: Amgen.
2. Yang B-B, et al. *Pharmacotherapy.* 2007;27:1387-1393.

NEUPOGEN® (FILGRASTIM)

Important Safety Information

Contraindication
NEUPOGEN® is contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors, such as filgrastim or pegfilgrastim.

Splenic Rupture
Splenic rupture, including fatal cases, has been reported following the administration of NEUPOGEN®. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome
Acute respiratory distress syndrome (ARDS) has been reported in patients receiving NEUPOGEN®. Evaluate patients who develop fever and lung infiltrates or respiratory distress for ARDS. Discontinue NEUPOGEN® in patients with ARDS

Serious Allergic Reactions
Serious allergic reactions, including anaphylaxis, have been reported in patients receiving NEUPOGEN®. The majority of reported events occurred upon initial exposure. Provide symptomatic treatment for allergic reactions. Allergic reactions, including anaphylaxis, in patients receiving NEUPOGEN® can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue NEUPOGEN® in patients with serious allergic reactions.

Sickle Cell Disorders
Sickle cell crisis, in some cases fatal, has been reported with the use of NEUPOGEN® in patients with sickle cell trait or sickle cell disease.

Glomerulonephritis
Glomerulonephritis has occurred in patients receiving NEUPOGEN®. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose reduction or discontinuation of NEUPOGEN®. If causality is likely, consider dose-reduction or interruption of NEUPOGEN®.

Capillary Leak Syndrome
Capillary leak syndrome has been reported after G-CSF administration, including NEUPOGEN®, and is characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency, severity, and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include the need for intensive care.

Thrombocytopenia
Thrombocytopenia has been reported in patients receiving NEUPOGEN®. Monitor platelet counts.

Leukocytosis
White blood cell counts of ≥ 100,000/mm^3 were observed in about 2% of patients with cancer receiving myelosuppressive chemotherapy who received NEUPOGEN® at dosages > 5 mcg/kg/day. It is recommended to monitor CBCs at least twice weekly, and adjust NEUPOGEN® dosing as clinically indicated to help mitigate risk of leukocytosis. Dosages of NEUPOGEN® that increase the absolute neutrophil count (ANC) beyond 10,000/mm^3 may not result in any additional clinical benefit. Discontinuation of NEUPOGEN® therapy usually resulted in a 50% decrease in circulating neutrophils within 1 to 2 days, with a return to pretreatment levels in 1 to 7 days.

Cutaneous Vasculitis
Cutaneous vasculitis has been reported in patients treated with NEUPOGEN®. In most cases, the severity of cutaneous vasculitis was moderate or severe. Most of the reports involved patients with severe chronic neutropenia (SCN) receiving long-term NEUPOGEN® therapy. Hold NEUPOGEN® therapy in patients with cutaneous vasculitis. NEUPOGEN® may be started at a reduced dose when the symptoms resolve and the absolute neutrophil count (ANC) has decreased.

Potential Effect on Malignant Cells
The granulocyte colony-stimulating factor (G-CSF) receptor through which filgrastim acts has also been found on tumor cell lines. The possibility that NEUPOGEN® acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, cannot be excluded.

Simultaneous Use with Chemotherapy and Radiation Therapy Not Recommended
The safety and efficacy of NEUPOGEN® given simultaneously with cytotoxic chemotherapy have not been established. Do not use NEUPOGEN® in the period 24 hours before or after the administration of cytotoxic chemotherapy. The safety and efficacy of NEUPOGEN® have not been evaluated in patients receiving concurrent radiation therapy. Avoid the simultaneous use of NEUPOGEN® with chemotherapy and radiation therapy.

Nuclear Imaging
Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone-imaging changes. This should be considered when interpreting bone-imaging results.

The most common adverse reactions (≥ 5% difference in incidence, compared to placebo) are anemia, constipation, diarrhea, oral pain, vomiting, asthenia, malaise, peripheral edema, decreased hemoglobin, decreased appetite, oropharyngeal pain, and alopecia.

Please see NEUPOGEN® full Prescribing Information.

AMGEN®

USA-002-106481(1)