# DRUG NAME: Pegfilgrastim

**SYNONYM(S)[1]:** pegylated granulocyte colony stimulating factor (G-CSF), G-CSF PEG conjugate

**COMMON TRADE NAME(S):** NEULASTA®, LAPELGA® (biosimilar), FULPHILA® (biosimilar), NIOPEG® (biosimilar), NYVEPRIA® (biosimilar), PEXEGRA® (biosimilar), ZIEXTENZO® (biosimilar)

**CLASSIFICATION:** miscellaneous

*Special pediatric considerations are noted when applicable, otherwise adult provisions apply.*

## MECHANISM OF ACTION:

Pegfilgrastim is a hematopoietic growth factor which regulates the production and function of neutrophils. Pegfilgrastim is composed of filgrastim (granulocyte colony stimulating factor, G-CSF) covalently bonded to polyethylene glycol (PEG). Compared to filgrastim, pegfilgrastim has a prolonged duration of effect due to reduced renal clearance. Pegfilgrastim increases the proliferation and differentiation of neutrophils from committed progenitor cells and induces maturation. Pegfilgrastim also stimulates the release of neutrophils from bone marrow storage pools, reduces maturation time, and enhances the phagocytic activity of mature neutrophils. In patients receiving cytotoxic chemotherapy, pegfilgrastim can accelerate neutrophil recovery, leading to a reduction in duration of the neutropenic phase.[1-3]

## PHARMACOKINETICS:

| | | |
|---|---|---|
| Distribution | not fully characterized | |
| | cross blood brain barrier? | no information found |
| | volume of distribution | no information found |
| | plasma protein binding | no information found |
| Metabolism | not fully characterized; pegfilgrastim binds to the G-CSF receptor on the neutrophil surface, creating a drug-receptor complex that is internalized to the endosomal compartments and either recycled or degraded[4,5] | |
| | active metabolite(s) | no information found |
| | inactive metabolite(s) | no information found |
| Excretion | primarily eliminated by neutrophil-mediated clearance[5] | |
| | urine | negligible[5] |
| | feces | no information found |
| | terminal half life | 25-49 h |
| | clearance | 6.7-17.7 mL/hr/kg |
| Sex | no clinically meaningful difference | |
| Elderly | no clinically meaningful difference | |

Adapted from standard reference[2] unless specified otherwise.

## USES:

***Primary uses:***

Prevention of chemotherapy-induced neutropenia*

***Other uses:***

*Health Canada approved indication



Developed: 1 June 2026
Revised:

## SPECIAL PRECAUTIONS:

***Contraindications:***
- history of hypersensitivity reaction to E. coli derived products, filgrastim, or pegfilgrastim[2]

***Caution:***
- The safety and efficacy of pegfilgrastim given ***simultaneously with cytotoxic chemotherapy*** has not been established.[2] Because pegfilgrastim stimulates the rapid proliferation of myeloid cells and these cells may be sensitive to cytotoxic chemotherapy, pegfilgrastim should not be administered in the period of 12 days before through 24 hours after the administration of cytotoxic chemotherapy.[6]
- Pegfilgrastim is a ***growth factor*** that primarily stimulates the production of neutrophils. However, the possibility that pegfilgrastim can act as a growth factor for certain tumour types cannot be excluded; use with caution in patients with myelodysplasia or in any malignancy with myeloid characteristics.[2,4]
- ***Sickle cell crisis*** has been associated with pegfilgrastim in patients with sickle cell trait or sickle cell disease[2]

***Carcinogenicity:*** No studies have been conducted. In animal studies, pegfilgrastim did not cause precancerous or cancerous lesions. Based on its similar biochemical activity to filgrastim, the nature of the PEG moiety, and extensive clinical experience with filgrastim, pegfilgrastim is unlikely to be carcinogenic.[2]

***Mutagenicity:*** No studies have been conducted with pegfilgrastim. Filgrastim was not mutagenic in Ames test.[2]

***Fertility:*** In animal studies, pegfilgrastim did not affect reproductive performance or fertility in male and female test subjects at exposures approximately 6 to 9 times higher than the expected human exposure with clinical doses.[2]

***Pregnancy:*** Available data on pegfilgrastim use in pregnant women are insufficient to establish a drug-associated risk. Published studies in pregnant women exposed to filgrastim products have not identified an association with major birth defects, miscarriage, or adverse fetal outcomes. Animal data appear to be species dependent. In rats, no fetal malformations were observed at exposures approximately 10 times the expected human exposure at recommended doses. Offspring of treated dams exhibited wavy ribs which is generally regarded as reversible pathological finding. In rabbits, decreased fetal body weight and delayed ossification of fetal skull were observed at exposures comparable to the expected human exposure; however, no structural malformations were observed. Increased post implantation loss and abortions were observed at exposures 4 times the expected human exposure at recommended doses, but these effects were not observed at exposures comparable to expected human exposure.[2,7]

***Breastfeeding*** is not recommended due to the potential secretion into breast milk.[2]

## SIDE EFFECTS:

The table includes adverse events that presented during drug treatment but may not necessarily have a causal relationship with the drug. Because clinical trials are conducted under very specific conditions, the adverse event rates observed may not reflect the rates observed in clinical practice. Adverse events are generally included if they were reported in more than 1% of patients in the product monograph or pivotal trials, and/or determined to be clinically important.[8-10] When placebo-controlled trials are available, adverse events will generally be included if the incidence is ≥5% higher in the treatment group.

| ORGAN SITE | SIDE EFFECT |
|---|---|
| Clinically important side effects are in ***bold, italics*** | |
| blood and lymphatic system/ febrile neutropenia | leukocytosis (1%) |
| | sickle cell crisis |
| | splenic rupture; see paragraph following **Side Effects** table |



Developed: 1 June 2026
Revised:

| ORGAN SITE | SIDE EFFECT |
|---|---|
| Clinically important side effects are in ***bold, italics*** | |
| | splenomegaly (<1%) |
| | thrombocytopenia (<1%) |
| cardiac | aortitis (<1%); see paragraph following **Side Effects** table |
| eye | periorbital edema (1%) |
| general disorders and administration site conditions | injection site reaction (3%); pain and bruising |
| immune system | hypersensitivity (<1%); see paragraph following **Side Effects** table |
| investigations | alkaline phosphatase increase, transient (11%) |
| | lactate dehydrogenase increase, transient (18%) |
| | uric acid increase, transient (10%) |
| musculoskeletal and connective tissue | arthralgia (6%) |
| | ***bone pain*** (13-21%); see paragraph following **Side Effects** table |
| | myalgia (7%) |
| neoplasms (see paragraph following **Side Effects** table) | acute myeloid leukemia (<1%) |
| | myelodysplastic syndrome (<1%) |
| nervous system | headache (1-4%) |
| renal and urinary | glomerulonephritis (<1%)[11] |
| respiratory, thoracic, and mediastinal | acute respiratory distress syndrome (<1%); see paragraph following **Side Effects** table |
| | alveolar hemorrhage[7,11] |
| skin and subcutaneous tissue | alopecia |
| | Sweet's syndrome |
| vascular | capillary leak syndrome (<1%); see paragraph following **Side Effects** table |
| | cutaneous vasculitis (<1%); see paragraph following **Side Effects** table |

Adapted from standard reference[2,11] unless specified otherwise.

***Bone pain*** is the most frequently reported adverse reaction of pegfilgrastim, with an incidence comparable to that observed with filgrastim.[2] It usually occurs within 2 days of pegfilgrastim administration and may last for 2-4 days. Most cases are mild to moderate in severity, with pain primarily affecting the back and legs.[12] Bone pain associated with G-CSF is thought to be the result of the marrow expansion that occurs from the increase in the neutrophil pool, which can cause a sensation of pressure or pain. Most cases of bone pain can be managed with non-narcotic analgesics.[2,6,13] Antihistamines (e.g., loratadine) have been used for prophylaxis or for the management of bone pain unresponsive to analgesics.[6,10,14]

***Capillary leak syndrome*** (CLS) has been reported in patients receiving pegfilgrastim. CLS can cause circulatory shock and is characterized by hypotension, generalized edema, hypoalbuminemia, and hemoconcentration. Episodes can vary in frequency and severity and may be life-threatening if treatment is delayed. If CLS is suspected, closely monitor patients as symptomatic treatment and/or intensive care may be required.[2]



Developed: 1 June 2026
Revised:

***Hypersensitivity***, including serious allergic reactions and anaphylaxis, has occurred during initial and subsequent treatments with pegfilgrastim. Reactions may include rash, urticaria, erythema/flushing, facial edema, wheezing, dyspnea, hypotension, and tachycardia. In rare cases, allergic reactions may recur within days after discontinuation of initial antiallergic treatment. Permanently discontinue pegfilgrastim after serious reactions.[2]

***Acute respiratory distress syndrome (ARDS)*** is reported in patients receiving pegfilgrastim and is postulated to occur secondary to an influx of neutrophils to sites of inflammation in the lungs. Patients who develop fever, lung infiltrates, or respiratory distress should be evaluated for ARDS. Pegfilgrastim should be withheld until resolution of symptoms or discontinued if necessary.[2]

***Splenic rupture***, including fatal cases, has been reported. Patients reporting left upper abdominal or shoulder tip pain should be evaluated for an enlarged spleen or splenic rupture.[2]

***Cutaneous vasculitis*** has been reported with pegfilgrastim. Clinical presentation may include petechiae, hives, itchy skin, and red spots or bumps.[2] Corticosteroids have been used for treatment of cutaneous vasculitis associated with filgrastim therapy.[15]

***Aortitis*** has been reported with pegfilgrastim and filgrastim. Clinical presentation may include fever, abdominal or back pain, malaise, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count). Aortitis may occur within 10 days of G-CSF administration and usually resolves within 14-16 days.[11,16]

***Acute myeloid leukemia*** and ***myelodysplastic syndrome*** have been reported with pegfilgrastim and filgrastim. However, a causal relationship has not been established.[2,6,17,18]

## INTERACTIONS:

| AGENT | EFFECT | MECHANISM | MANAGEMENT |
|---|---|---|---|
| myelosuppressive[2] chemotherapy | decreased effectiveness of pegfilgrastim | rapidly dividing myeloid cells (stimulated by pegfilgrastim) may be destroyed by chemotherapy | do not administer concurrently; pegfilgrastim should not be administered in the period 12 days **before** through 24 hours **after** the administration of myelosuppressive chemotherapy |

## SUPPLY AND STORAGE:

***Biosimilar*** formulations of pegfilgrastim are available.

***Injection*:**

Amgen Canada Inc. supplies pegfilgrastim (NEULASTA®) as 0.6 mL single-use (preservative free) prefilled syringes in a concentration of 10 mg/mL. Refrigerate. Protect from light. Avoid vigorous shaking. The needle cover of the prefilled syringe contains natural rubber (a derivative of latex).[19]

Apotex Inc. supplies pegfilgrastim (LAPELGA®) as 0.6 mL single-use (preservative free) prefilled syringes and autoinjectors in a concentration of 10 mg/mL. Refrigerate. Protect from light. Avoid vigorous shaking.[2]

Biocon Biologics (Biosimilar Collaborations Ireland Limited)/ BGP Pharma ULC supplies pegfilgrastim (FULPHILA®) as 0.6 mL single-use (preservative free) prefilled syringes in a concentration of 10 mg/mL. Refrigerate. Protect from light. Avoid vigorous shaking.[20]



Developed: 1 June 2026
Revised:

Nora Pharma Inc. supplies pegfilgrastim (NIOPEG®) as 0.6 mL single-use (preservative free) prefilled syringes in a concentration of 10 mg/mL. Refrigerate. Protect from light. Avoid vigorous shaking.[21]

Pfizer Canada ULC supplies pegfilgrastim (NYVEPRIA®) as 0.6 mL single-use (preservative free) prefilled syringes in a concentration of 10 mg/mL. Refrigerate. Protect from light. Avoid vigorous shaking.[22]

Jamp Pharma Corporation supplies pegfilgrastim (PEXEGRA®) as 0.6 mL single-use (preservative free) prefilled syringes in a concentration of 10 mg/mL. Refrigerate. Protect from light. Avoid vigorous shaking.[23]

Sandoz Canada Inc. supplies pegfilgrastim (ZIEXTENZO®) as 0.6 mL single-use (preservative free) prefilled syringes in a concentration of 10 mg/mL. Refrigerate. Protect from light. Avoid vigorous shaking.[24]

***Additional information:***
- if accidentally frozen, allow to thaw in the refrigerator before administration; discard if frozen more than once
- maximum single storage period at room temperature prior to use; discard if not used within this time period:
  - NEULASTA®: 3 days[19]
  - LAPELGA®: 15 days[2]
  - FULPHILA®: 3 days[20]
  - NIOPEG®: 4 days[21]
  - NYVEPRIA®: 15 days[22]
  - PEXEGRA®: 3 days[23]
  - ZIEXTENZO®: 5 days[24]

## PARENTERAL ADMINISTRATION:

BC Cancer administration guideline noted in ***bold***, ***italics***

| ***Subcutaneous*** | ***SC injection*** into the abdomen (except within 2 inches of navel), thighs, upper arms, or buttocks; alternate injections sites with each injection[2]<br><br>Refrigerated syringes: allow to reach room temperature about 30 min prior to administration[2] |
|---|---|
| Intramuscular | do NOT use |
| Direct intravenous | do NOT use |
| Intermittent infusion | do NOT use |
| Continuous infusion | do NOT use |
| Intraperitoneal | do NOT use |
| Intrapleural | do NOT use |
| Intrathecal | do NOT use |
| Intra-arterial | do NOT use |
| Intravesical | do NOT use |

## DOSAGE GUIDELINES:

Refer to protocol by which patient is being treated.



Developed: 1 June 2026
Revised:

***Adults*:**

BC Cancer usual dose noted in ***bold, italics***

| | |
|---|---|
| *subcutaneous*[2,6]*:* | ***6 mg SC for one dose*** per chemotherapy cycle, given 24-72 hours after the administration of chemotherapy (total dose per cycle= 6 mg)<br><br>A minimum interval of 12 days between pegfilgrastim administration and the next chemotherapy dose is recommended[6]; shorter intervals (i.e., 10-11 days) have been used[25-29] |
| *Concurrent radiation:* | not studied; has been used[2] |
| *Dosage in renal failure:* | renal impairment, including end-stage renal disease: no adjustment required[2] |
| *Dosage in hepatic failure:* | no information found |
| *Dosage in dialysis:* | no information found |

***Children:***

| | |
|---|---|
| *subcutaneous*[7]*:* | Administer one dose per each chemotherapy cycle. Refer to protocol by which patient is being treated. If no protocol is available, the following may be used as a guideline:<br><br><10 kg: 0.1 mg/kg SC<br>10-20 kg: 1.5 mg SC<br>21-30 kg: 2.5 mg SC<br>31-45 kg: 4 mg SC<br>>45 kg: 6 mg SC |

## REFERENCES:


1. Lexi-Drugs® (database on the Internet). Pegfilgrastim. UpToDate® Lexidrug®; Accessed April 15, 2026. Updated November 11, 2025. Available at: http://online.lexi.com
2. Apotex Inc. LAPELGA® product monograph. Toronto, Ontario; January 29, 2026.
3. Hollingshead LM, Goa K. Recombinant granulocyte colony-stimulating factor (rG-CSF): A review of its pharmacological properties and prospective role in neutropenic conditions. Drugs ; 1991;42:300–330
4. Amgen Canada Inc. NEUPOGEN® product monograph. Mississauga, Ontario; May 5, 2023.
5. Yang B, Kido A. Pharmacokinetics and Pharmacodynamics of Pegfilgrastim. Clin.Pharmacokinet. ; 2011;50(5):295–306
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology - Hematopoietic Growth Factors v.3.2026. National Comprehensive Cancer Network; Accessed April 27, 2026. December 5, 2025. Available at: http://www.nccn.org
7. Amgen Inc. NEULASTA® full prescribing information. Thousand Oaks, California, USA; August 18, 2025.
8. Orysya Fetterly, Tumour Group Pharmacist. Provincial Pharmacy. Personal Communication. May 3, 2026.
9. Michelle LaFreniere. Provincial Oncology Educator. Professional Practice Nursing BC Cancer. Personal Communication. May 13, 2026.
10. Levasseur N MD. Medical oncologist, BC Cancer Breast Tumour Group. Personal Communication. May 29, 2026.
11. Amgen Europe BV. NEULASTA® Summary of Product Characteristics. Breda, The Netherlands; June 28, 2024.
12. Moukharskaya J, Abrams DM, Ashikaga T, et al. Randomized Phase II Study of Loratadine for the Prevention of Bone Pain caused by Pegfilgrastim. Supportive Care in Cancer ; 2016;24(7):3085–3093
13. Moore DC, Pellegrino AE. Pegfilgrastim-Induced Bone Pain: A Review on Incidence, Risk Factors, and Evidence-Based Management. Ann.Pharmacother. ; 2017;51(9):797–803




Developed: 1 June 2026
Revised:

14. Kirshner JJ, McDonald MC, Kruter F, et al. NOLAN: a randomized, phase 2 study to estimate the effect of prophylactic naproxen or loratadine vs no prophylactic treatment on bone pain in patients with early-stage breast cancer receiving chemotherapy and pegfilgrastim. Supportive Care in Cancer ; 2018;26(4):1323–1334
15. Jain KK. Cutaneous vasculitis associated with granulocyte colony-stimulating factor. J Am Acad Dermatol ; 1994;31(2 part 1):213–215
16. Hoshina H, Takei H. Granulocyte-Colony Stimulating Factor-associated Aortitis in Cancer: A Systematic Literature Review. Cancer Treatment and Research Communications ; 2021;29:100454
17. Tigue CC, McKoy JM, Evens AM, et al. Granulocyte-colony stimulating factor administration to healthy individuals and persons with chronic neutropenia or cancer: an overview of safety considerations from the Research on Adverse Drug Events and Reports project. Bone marrow transplantation (Basingstoke) ; 2007;40(3):185–192DOI: https:10.1038/sj.bmt.1705722
18. Lyman GH, Dale DC, Wolff DA, et al. Acute Myeloid Leukemia or Myelodysplastic Syndrome in Randomized Controlled Clinical Trials of Cancer Chemotherapy With Granulocyte Colony-Stimulating Factor: A Systematic Review. Journal of Clinical Oncology ; 2010;28(17):2914–2924
19. Amgen Canada Inc. NEULASTA® product monograph. Mississauga, Ontario; January 8, 2021.
20. Biocon Biologics (Biosimilar Collaborations Ireland Limited)/ BGP Pharma ULC. FULPHILA® product monograph. Etobicoke, Ontario; May 15, 2023.
21. Nora Pharma Inc. NIOPEG® product monograph. Varennes, Quebec; April 17, 2024.
22. Pfizer Canada ULC. NYVEPRIA® product monograph. Kirkland, Quebec; February 14, 2022.
23. JAMP Pharma Corporation. PEXEGRA® product monograph. Boucherville, Québec; December 13, 2024.
24. Sandoz Canada Inc. ZIEXTENZO® product monograph. Boucherville, Québec; June 10, 2024.
25. Hecht JR, Pillai M, Gollard R, et al. A Randomized, Placebo-Controlled Phase II Study Evaluating the Reduction of Neutropenia and Febrile Neutropenia in Patients With Colorectal Cancer Receiving Pegfilgrastim With Every-2-Week Chemotherapy. Clinical Colorectal Cancer ; 2010;9(2):95–101
26. Zwick C, Hartmann F, Zeynalova S, et al. Randomized Comparison of Pegfilgrastim Day 4 versus Day 2 for the Prevention of Chemotherapy-induced Leukocytopenia. Annals of Oncology ; 2011;22(8):1872–1877
27. Lane SW, Crawford J, Kenealy M, et al. Safety and efficacy of pegfilgrastim compared to granulocyte colony stimulating factor (G-CSF) supporting a dose-intensive, rapidly cycling anti-metabolite containing chemotherapy regimen (Hyper-CVAD) for lymphoid malignancy. Leuk.Lymphoma ; 2006;47(9):1813–1817
28. Pirker R, Ulsperger E, Messner J, et al. Achieving Full-Dose, On-Schedule Administration of ACE Chemotherapy Every 14 Days for the Treatment of Patients with Extensive Small-Cell Lung Cancer. Lung ; 2006;184(5):279–285
29. Donkor KN, Selim JH, Waworuntu A, et al. Safety and Efficacy of Pegfilgrastim When Given Less Than 14 Days Before the Next Chemotherapy Cycle: Review of Every 14-Day Chemotherapy Regimen Containing 5-FU Continuous Infusion. Ann.Pharmacother. ; 2017;51(10):840–847



Developed: 1 June 2026
Revised: