INDICATION
Fulphila® 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 clinically significant incidence of febrile neutropenia.
Fulphila® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

IMPORTANT SAFETY INFORMATION
Do not administer Fulphila® to patients with a history of serious allergic reactions, including anaphylaxis, to pegfilgrastim or filgrastim.
Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim products. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving Fulphila®.
For FDA approval, Fulphila® had to demonstrate that it is highly similar to an existing FDA-approved biological product referred to as the reference product or reference biologic.

Acute respiratory distress syndrome (ARDS) can occur in patients receiving pegfilgrastim products. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Fulphila® for ARDS. Discontinue Fulphila® in patients with ARDS.

Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products. The majority of reported events occurred upon initial exposure and can recur within days after discontinuation of initial anti-allergic treatment. Permanently discontinue Fulphila® in patients with serious allergic reactions to any pegfilgrastim or filgrastim products.

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim products. Discontinue if sickle cell crisis occurs.

Glomerulonephritis has been reported in patients receiving pegfilgrastim products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after withdrawal of pegfilgrastim products. If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of Fulphila®.

Confirmatory Phase III study demonstrated equivalent efficacy to the reference product in the reduction of chemotherapy-induced febrile neutropenia in breast cancer patients

± SD Absolute Neutrophil Count Over Time by Treatment in Cycle 1 (PP Population)

**STUDY DESIGN:** Randomized, double-blind, parallel-group trial evaluating equivalence of Fulphila® vs reference pegfilgrastim in patients with breast cancer eligible to receive neoadjuvant or adjuvant TAC chemotherapy. The primary endpoint was the duration of severe neutropenia in cycle 1 defined as ANC < 0.5 x 10^9/L. Of 207 patients screened, 194 were randomized; 127 received MYL-1401H and 67 received reference pegfilgrastim.

**IMPORTANT SAFETY INFORMATION**

White blood cell counts of 100 x 10^9/L or greater have been observed in patients receiving pegfilgrastim products. Monitoring of CBCs during therapy with Fulphila® is recommended.


Please see back cover for complete summary of Important Safety Information.
A team of dedicated patient access specialists is available to answer calls and address concerns or questions regarding:

**CODING AND BILLING INFORMATION**
- Provide information about applicable coding for Fulphila® (pegfilgrastim-jmdb) and its administration.
  **Note:** Coding information is provided for informational purposes only and the physician must determine the appropriate code for each patient and payer.

**INSURANCE COVERAGE VERIFICATION**
- Check patient insurance plan enrollment status.

**BENEFIT INVESTIGATION**
- Research patient-specific insurance coverage, coding, and billing requirements for Fulphila® and its administration.
- Verify patient cost-sharing requirements including deductible, copay, coinsurance, and out-of-pocket maximum, and amounts met to date.
- Determine payer access requirements (e.g., specialty pharmacy, in-office dispensing, etc).
- Prepare Summary of Benefits that documents all findings.

**PRIOR AUTHORIZATION (PA)/REAUTHORIZATION ASSISTANCE & TRACKING**
- Check PA requirements, submission details, and track status.
- Provide offices with payer-specific forms.

**REVIEWED AND ENDORSED BY**:

**COVERAGE/CLAIM APPEAL ASSISTANCE & TRACKING**
- Verify appeal requirements.
- Track status and resolution of appeals.

Please see back cover for complete summary of Important Safety Information.
COPAY ASSISTANCE

• Commercially insured patients may be able to access Fulphila® for a $0 copay
• No income restrictions
• Eligibility criteria apply; see below for additional details

CO-PAY TERMS AND CONDITIONS

The MYLAN ADVOCATE™ Co-Pay Assistance Program is open to both new and existing eligible patients who are residents of the U.S. or Puerto Rico and who have commercial insurance.

This co-pay assistance program can be used to reduce the amount of an eligible patient’s out-of-pocket expense for Mylan’s Fulphila® up to the full amount of the patient’s out-of-pocket expense per prescription up to $10,000 per 12-month period.

This co-pay assistance program is not valid for uninsured patients or patients whose commercial insurance coverage does not include Fulphila®; patients who are covered in whole or in part by any state or federally funded healthcare program, including, but not limited to, any state pharmaceutical assistance program, Medicare (Part D or otherwise), Medicaid, Medigap, VA or DOD, or TriCare (regardless of whether a specific prescription is covered by such government program); if the patient is Medicare eligible and enrolled in an employer-sponsored health plan or prescription benefit program for retirees; or if the patient’s insurance plan is paying the entire cost of this prescription. This co-pay assistance program is void outside the U.S. or Puerto Rico or in any state or jurisdiction where prohibited by law, taxed, or restricted. This program is valid in Massachusetts through June 30, 2019, unless applicable law is amended or extended by Massachusetts.

Valid prescription required. Use of this co-pay assistance program must be consistent with the terms of any drug benefit provided by a commercial health insurer, health plan, or private third-party payer. This co-pay assistance program may be changed or discontinued at any time without notice.

This co-pay assistance program is not health insurance. The co-pay assistance program is not transferable and the amount of the benefit cannot exceed the patient’s out-of-pocket expenses. Cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. The co-pay assistance is not redeemable for cash. No additional purchase is required.

Data related to use of this co-pay assistance program may be collected, analyzed, and shared with Mylan for market research and other purposes related to assessing co-pay assistance programs. Data shared with Mylan will be aggregated and de-identified, meaning it will be combined with data related to other co-pay assistance program redemptions and will not identify you.

Patients are responsible for reporting the receipt of co-pay assistance to any insurer, health plan, or third-party payer who pays for or reimburses any part of the prescription filled, as may be required. Patients should not use this program if their health plan prohibits use of manufacturer co-pay assistance programs.

PATIENT ASSISTANCE

• Patients without insurance coverage for Fulphila® who cannot afford their medication may be able to receive their medication free of charge
• Eligibility requirements apply based on residency, income, and other factors. Contact MYLAN ADVOCATE™ for more information

FIELD REIMBURSEMENT SUPPORT

• A reimbursement expert from your area can visit your practice or clinic for live educational programs on coverage and reimbursement information or to assist with questions related to Fulphila® access for patients

ALTERNATE COVERAGE IDENTIFICATION

• MYLAN ADVOCATE™ can help identify other resources, such as state programs or third-party charitable foundations, that may be able to assist your patients

Call Monday – Friday between the hours of 9:00 AM to 8:00 PM ET toll-free at: 1 (833) 695-2623
Online go to: www.mylanadvocate.com

Please see back cover for complete summary of Important Safety Information.
**Fulphila**
(pegfilgrastim-jmdb) injection

The First FDA-approved Biosimilar for Neulasta® (pegfilgrastim)

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**Product Name**
Fulphila® (pegfilgrastim-jmdb) injection

**NDC**
67457-833-06

**Strength**
6 mg/0.6 mL

**Pack Size**
One sterile 6 mg/0.6 mL prefilled syringe

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Glomerulonephritis has been reported in patients receiving pegfilgrastim products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after withdrawal of pegfilgrastim products. If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of Fulphila®.

White blood cell counts of 100 x 10⁹/L or greater have been observed in patients receiving pegfilgrastim products. Monitoring of CBCs during therapy with Fulphila® is recommended.

Capillary leak syndrome has been reported after granulocyte colony-stimulating factor (G-CSF) administration, including pegfilgrastim products, 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 a need for intensive care.

The G-CSF receptor, through which pegfilgrastim and filgrastim products act, has been found on tumor cell lines. The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded.

Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy. Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., C-reactive protein and white blood cell count). Consider aortitis in patients who develop these signs and symptoms without known etiology and discontinue Fulphila® if aortitis is suspected.

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) in placebo-controlled clinical trials are bone pain and pain in extremity.

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Please see Important Safety Information and accompanying Full Prescribing Information

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Neulasta® is a registered trademark of Amgen Inc.