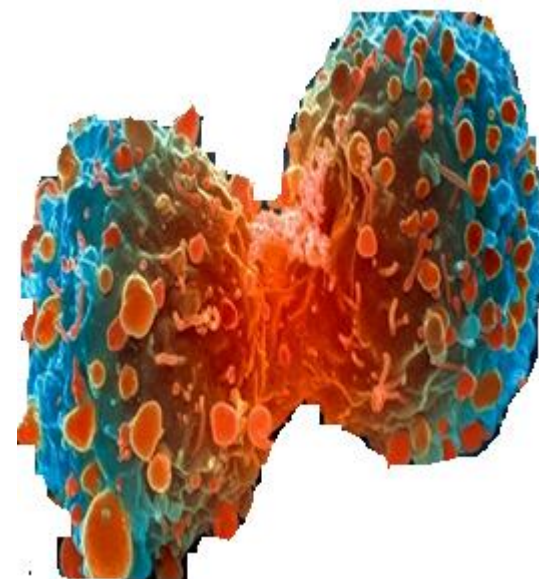


# US FDA approves Fulphila as first biosimilar to Neulasta drug which helps to reduce the risk of infection during cancer treatment on 4<sup>th</sup> June 2018



New FDA Approved  
**Biosimilar**

Fulphila (6 mg/ 0.6 ml)  
Pegfilgrastim- jmdb



A biosimilar is a biological product that is approved based on data showing that it is highly similar to a biological product already approved by the FDA (reference product) and has no clinically meaningful differences in terms of safety, purity and potency (i.e., safety and effectiveness) from the reference product, in addition to meeting other criteria specified by law.

# Non- Myeloid Cancer- Disease Burden

## What is Non- Myeloid Cancer

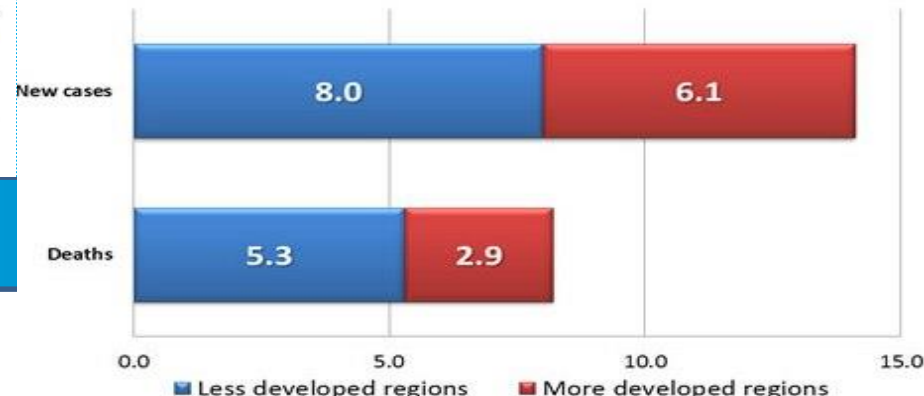
- All cancers other than myeloid leukemias. These non- myeloid cancers include all type of carcinoma, sarcoma, melanoma, lymphomas, lymphomatic leukemias and multiple myeloma.
- **Symptoms include but not limited to:** Weight loss, Fatigue, Fever, Night sweats, Loss of appetite



## Facts and Figures

- In 2012, an estimated 14.1 million new cases of cancer occurred **worldwide**. ... Lung cancer is the most common cancer in men **worldwide**. More than 1 in 10 of all cancers diagnosed in men are lung cancers.
- The annual incidence of **CANCER** rates in India was originally reported to be 0.8 to 2.2 per 100,000 population. A recent study from the Mumbai Cancer Registry specifically examined Cancer and reported an age-adjusted rate (AAR; per 100,000) of 0.71 in males and 0.53 in females.

Number of Cancer Cases and Deaths Worldwide in 2012 (in millions)



# Market Overview - Infection

## Current Treatment options

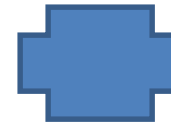
1. Antibiotic Prophylaxis.
2. Patient Hygiene.
3. Low Molecular Diet.
4. Screening for transmitted diseases.
5. Vaccination Programme.
6. Visitation Restriction.
7. Environmental Hygiene.



## Competitive landscape for Fulphila



Coherus



Novartis

1. **Coherus Biosciences** ([CHRS](#)) and **Novartis** ([NVS](#)) are working on biologic copies of Neulasta.
2. Coherus' Neulasta biosimilar will go before the FDA in November. Later, Novartis and its partner Apotex will have updates. A second U.S.-approved biosimilar of Neulasta would create increased competition and potential price headwinds,

# About Fulphila (Pegfilgrastim- jmdb)

## About the BLA Holder

- Mylan N.V. and Biocon announced on that the U.S. Food and Drug Administration has approved Mylan's Fulphila, a biosimilar to Neulasta, co-developed with Biocon to treat low count of neutrophils in patients undergoing chemotherapy in certain types of cancer.

## Brief on Fulphila

- Fulphila is a leukocyte growth factor indicated to • Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- **Limitations of Use:** Fulphila is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

**FULPHILA**  
(pegfilgrastim-jmdb)

**FDA** **APPROVED**



# About Fulphila(Pegfilgrastim- jmdb)

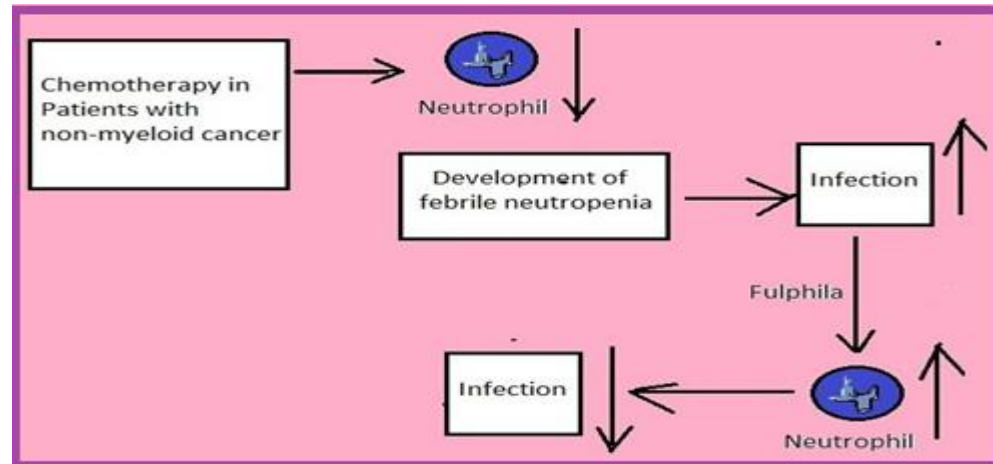
## Product information

- **Available strength:** 6 mg/ 0.6 ml
- **Route of Administration:**  
Subcutaneous
- **Site of Administration:** Thigh ,  
Stomach area (abdomen)- except for a  
2-inch area right around the navel  
(belly button), Upper outer area of the  
Buttocks (only if someone else is giving  
you the injection), and the Outer area  
of the Upper arm (only if someone else  
is giving you the injection).



## Mechanism of action

- Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.





[www.pharmastate.com](http://www.pharmastate.com)

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