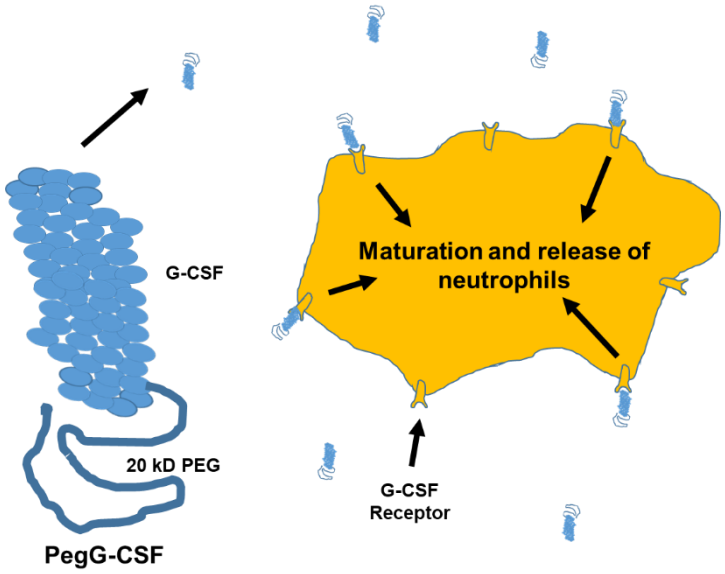
# pegG-CSF – Fact Sheet

## Molecule

Pegfilgrastim (pegylated granulocyte colony stimulating factor, pegG-CSF, Neulasta®) is a variant of G-CSF coupled to a polyethylene glycol (PEG) moiety at the N-terminus of human G-CSF. This pegylated form has a longer half-life, thus reducing the necessity of daily injections (half-life extended from 3.5 h to 15 h - 80 h). G-CSF consists of 175 amino acid residues (18.8 kDa) and is manufactured in E. coli. PEG tailing adds 20 kDa to the molecular weight of G-CSF.

## Mode of Action

Pegfilgrastim binds to the G-CSF receptor, stimulates the proliferation of progenitor cells and their maturation into neutrophils. Pegfilgrastim also stimulates the release of neutrophils from bone marrow and increases their phagocytic activity. Pegfilgrastim treatment can thus be applied to fight against infection in patients undergoing chemotherapy.




## Indication

Indications for pegfilgrastim are to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelo-suppressive anticancer drugs associated with clinically significant incidence of febrile neutropenia, and to increase survival in patients acutely exposed to myelo-suppressive doses of radiation.

## Patent Situation

The patents on Neulasta® expired in US in October 2015 and in Europe in August 2017. In December 2014, Apobiologix already submitted its biosimilar Lapelga® to FDA for approval and triggered a patent infringement litigation from Amgen, however, in September 2016 won the lawsuit.

## Market and Competitive Field

The originator product, Amgen's Neulasta®, was a co-development with Kyowa Hakko Kirin and was approved by FDA in January 2002 and by EMA in March 2002. In 2020, Neulasta® had worldwide sales of 1.93 billion € decreasing from 2.94 billion € in 2019. A "biobetter" variant is marketed by Teva (Israel) and a variety of biosimilar candidates are already in development or approved.

VelaLabs GmbH
Brunner Straße 69 / Obj. 3, A-1230 Vienna / Austria
Phone: +43 1 890 5979 11, Fax: +43 1 890 5979 10
E-Mail: office@vela-labs.at

| | pegG-CSF |
|---|---|
| | Neulasta® |
| | Fulphila™, Lapelga™, Peg-Neutropine®, Pelgraz™, Pelmeg®, Udenyca™, Ziextenzo™ |
| **Clone selection/ comparability** | |
| Affinity to recombinant target – kinetics (Biacore) | G-CSF-R |
| Cell-based bioassay | |
| **(Pre)clinical application** | |
| Pharmacokinetics (ECL or ELISA) | |
| Immunogenicity (Biacore/ ELISA/ bioassay) | |
| **Batch release EU** | |

Vela Portfolio

VelaLabs GmbH
Brunner Straße 69 / Obj. 3, A-1230 Vienna / Austria
Phone: +43 1 890 5979 11, Fax: +43 1 890 5979 10
E-Mail: office@vela-labs.at