Generic Name:
Filgrastim-aafi
Trade Name:
Nivestym
Company:
Pfizer
Notes:

FDA has approved filgrastim-aafi, a biosimilar to Neupogen (filgrastim), under the trade name Nivestym.

Approval was based on a review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity of Nivestym compared to its reference product.

In the United States, it is indicated for the following: 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; to reduce the time to neutrophil recovery and duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML; to reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g., febrile neutropenia) in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT); for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and for chronic administration to reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Common adverse effects include aching in the bones and muscles.

Serious risks include spleen enlargement and rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions, sickle cell crises, and kidney injury.

Medication Monitor Categories:
New Drug Approvals