Neupogen® (filgrastim) and Neulasta® (pegfilgrastim) – New warning

- On June 18, 2018, the FDA approved an update to the *Warnings and Precautions* sections of the Neupogen (filgrastim) and Neulasta (pegfilgrastim) drug labels regarding aortitis.

- Neupogen 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 significant incidence of severe neutropenia with fever
  - Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia
  - Reduce the duration of neutropenia and neutropenia-related clinical sequelae, eg, febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
  - Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
  - Reduce the incidence and duration of sequelae of severe neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
  - Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).

- Neulasta is 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
  - Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)
  - Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

- Aortitis has been reported in patients receiving Neupogen or Neulasta. 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 (eg, C-reactive protein and white blood cell count).

  - Consider aortitis in patients who develop these signs and symptoms without known etiology.
  - Discontinue Neupogen or Neulasta if aortitis is suspected.