

[Home](#) > Sandoz receives approval for pegfilgrastim biosimilar

Generic Name:

Pegfilgrastim-bmez

Trade Name:

Ziextenzo

Company:

Sandoz

Notes:

Sandoz [announced](#) FDA approval of pegfilgrastim-bmez, its biosimilar to pegfilgrastim (Neulasta), to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Pegfilgrastim is a long-acting form of filgrastim, which is very similar to a natural protein, granulocyte-colony stimulating factor, produced by a person's own body.

The recommended dosage for patients with cancer receiving myelosuppressive chemotherapy is 6 mg administered subcutaneously once per chemotherapy cycle. The agent should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Weight-based dosing should be used for pediatric patients weighing less than 45 kg; see the [prescribing information](#) for instructions.

Warnings and precautions include fatal splenic rupture; acute respiratory distress syndrome; serious allergic reactions, including anaphylaxis; fatal sickle cell crises; and glomerulonephritis.

The drug's most common adverse reactions are bone pain and pain in extremity.

Medication Monitor Categories:

[Supplemental Approvals](#)

Source URL: <https://www.aphadruginfoline.com/supplemental-approvals/sandoz-receives-approval-pegfilgrastim-biosimilar>