FDA APPROVED

Pfizer Injectables

nivestim™
filgrastim

Proven G-CSF for hospital and home

Now your patients can be engaged in a therapeutic alliance

- Choice of treatment at home or at hospital[1-6]
- Proven effective and well-tolerated in the real world setting*[1]
- Thermal stability, ie. 1 week non-refrigerated storage (25)˚C for one single period,[2,3] provides wide margin of safety buffer for travel and later use

*VENICE (Compatibility of Biosimilar Filgrastim with Cytotoxic Chemotherapy during the Treatment of Malignant Diseases) was a prospective, multicentre, non-interventional, longitudinal, observational study that enrolled adult patients (N = 386) with solid tumours or haematologic malignancies where cytotoxic chemotherapy and treatment with Nivestim was planned.

It is proven effective and well-tolerated in both the primary and secondary prophylactic setting in patients undergoing CT for solid tumors and hematological malignancies.

Wide margin of product stability, ease of use and convenient design for self-administered treatment[1-6]

Integrated needle-safe device[2,4]
Reduces risk of needle-stick injury

Pre-filled syringe[2,5,6]
Provides accurate dosage, convenience and time saving

7 days out-of-fridge stability[2,3]
Can be stored at up to 25˚C for a single period of up to 7 days

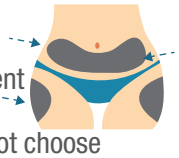
Simple Steps to Administering nivestim™ 7 filgrastim

STEP1: Get Nivestim™ ready
- Take Nivestim out of the fridge 15–30 minutes before use

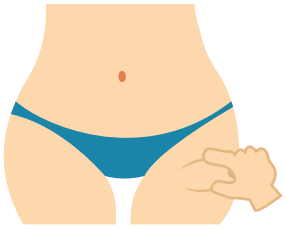
STEP2: Wash and check
- Wash hands thoroughly with soap and water.
- Check that the medicine is not expired and the solution is clear, colourless and free from visible particles or for any leaks.

STEP3: Unpack and uncap
- Remove syringe from blister pack,
- Remove the protective cap carefully

STEP4: Choose injection site
- Recommended areas are front of thighs or stomach
- Choose a different injection site each time. Do not choose an area which is tender, red, bruised or scarred.

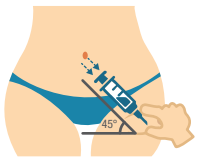


STEP5: Pinch skin
- Pinch a large area of skin

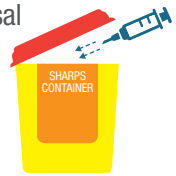


STEP6: Inject
- Insert the needle at a 45° angle
- Pull the plunger back slightly to check for blood. If any blood appears remove and re-insert in a different site
- Slowly push the plunger down until the syringe is empty

STEP7: Remove needle, press site
- Remove the needle
- Press firmly on the injection site



STEP8: Dispose syringe safely
- Place used syringe into the sharps bin (safe disposal container)



Nivestim™: Proven easy or very easy to self-administer in the real world setting[1]

- 77.7% of patients in a study self-administered own treatment on 1st visit
- Most patients find self-administration with Nivestim™ easy or very easy

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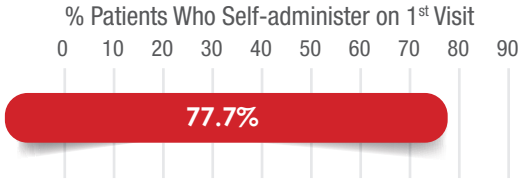
It is proven effective and well-tolerated in both the primary and secondary prophylactic setting in patients undergoing CT for solid tumors and hematological malignancies.

Majority of patients administered Nivestim™ themselves[1]



Abbreviated prescribing information for Hospira™ Nivestim™ filgrastim (rbe)[8]

Indication & Dosage: Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (except chronic myeloid leukemia and myelodysplastic syndrome); 0.5 MU (5 micrograms)/kg/day, do not give first dose <24hours following cytotoxic chemotherapy. Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation; initially 1.0 MU (10micrograms)/kg/day. Mobilization of peripheral blood progenitor cells (PBPC) in patients undergoing myelosuppressive or myeloablative therapy followed by autologous peripheral blood progenitor cell transplantation, and in normal donors prior to allogeneic PBPC transplantation; monotherapy dose is 1.0 MU (10 micrograms)/kg/day. In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of <0.5x109/L and a history of severe or recurrent infections; *congenital neutropenia*: the recommended starting dose is 1.2 MU (12 micrograms)/kg/day; *idiopathic or cyclic neutropenia*: the recommended starting dose is 0.5 MU (5 micrograms)/kg/day. For the treatment of persistent neutropenia (ANC less than or equal to 1.0x109/L) in patients with advanced HIV infection; *reversal of neutropenia*: the recommended starting dose is 0.1 MU (1 microgram)/kg/day, maximum of 0.4 MU (4 micrograms)/kg/day; *maintaining normal neutrophil count*: initial dose adjustment to alternate day dosing with 30 MU (300 micrograms)/day. **Contraindication:** Hypersensitivity to the active substance(s) or to any of the excipients. **Adverse reaction:** Elevated alkaline phosphatase, elevated LDH, elevated uric acid, headache, cough, sore throat, nausea/vomiting, constipation, anorexia, diarrhea, mucositis, elevated GGT, alopecia, skin rash, chest pain, musculoskeletal pain, fatigue, thrombocytopenia, decreased glucose, generalized weakness, anaemia, splenomegaly, epistaxis, hepatomegaly, cutaneous vasculitis, injection site pain, osteoporosis, leukocytosis, spleen disorder. **Precaution:** Do not use to increase the dose of cytotoxic chemotherapy or in patients with severe congenital neutropenia with abnormal cytogenetics. Malignant cell growth. Secondary AML. Monitoring of bone density. Rare pulmonary adverse events in particular interstitial pneumonia. Leukocytosis. High dose chemotherapy. Patients with substantially reduced myeloid progenitors. Patients receiving G-CSF after allogeneic bone marrow transplantation. Known cases of Hereditary Fructose Intolerance. Mobilisation. Prior exposure to cytotoxic agents. Assessment of progenitor cell yields. Normal donors undergoing PBPC <16 or >60 years. Transient thrombocytopenia and leukapheresis. Effect on GvHD not defined, splenomegaly, pulmonary adverse events in normal donors, blood cell counts, transformation to leukaemia or myelodysplastic syndrome. Neonates and patients with autoimmune neutropenia. Infections and malignancies causing myelosuppression. Sickle cells crises. **Presentation:** Clear, colourless solution for injection/infusion, available in 300µg/0.5mL x 10 pre-filled syringes. API-NIVESTIM-0914

Full prescribing information is available upon request.

References :

1. Fruehauf S, Otremba B, Stötzer O, Rudolph C. Compatibility of biosimilar filgrastim with cytotoxic chemotherapy during the treatment of malignant diseases (VENICE): A prospective, multicenter, non-Interventional, longitudinal study. Advances in Therapy 2016;33(11):1983-2000. 2. Nivestim™ filgrastim (rbe) Hospira™ PI, September 2014. 3. Kamioner D, Fruehauf S, Maloisel F, Cals L, Lepretre S, Berthou C. Study design: two long-term observational studies of the biosimilar filgrastim Nivestim™(Hospira filgrastim) in the treatment and prevention of chemotherapy-induced neutropenia. BMC Cancer. 2013 Dec;13(1):547. 4. Longworth A. Developments in the packaging of pre-filled syringes. European Journal of Parenteral & Pharmaceutical Sciences 2009;14(2):35. 5. Makwana S, Basu B, Makasana Y, Dharamsi A. Prefilled syringes: An innovation in parenteral packaging. International Journal of Pharmaceutical Investigation. 2011 Oct;1(4):200. 6. Badkar A, Wolf A, Bohack L, Kolhe P. Development of biotechnology products in pre-filled syringes: Technical considerations and approaches. AAPS Pharmscitech. 2011 Jun 1;12(2):564-72. 7. Electronic Medicines Compendium (eMC). Nivestim package leaflet: information for the user. Available at https://www.medicines.org.uk/emc/files/pil.575.pdf. Accessed 2 June 2018. 8. Abbreviated prescribing information for Hospira™ Nivestim™ filgrastim (rbe). API-NIVESTIM-0914.

For healthcare professionals only.

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