Filgrastim - biosimilar (Brand as per Trust contract)

Indications

Reduction in duration of neutropenia and incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (except CML and MDS).

Reduction in duration of neutropenia in patients undergoing myeloablative therapy followed by BMT considered at increased risk of prolonged severe neutropenia.

Mobilisation of peripheral blood progenitor cells following cytotoxic chemotherapy – Myeloma, Lymphoma.

Pre-assessment – as per chemotherapy protocol.

Drug regimen

Start day and duration: As per local protocol / policy.
First dose should NOT be administered less than 24 hours following cytotoxic chemotherapy / within 24 hours of peripheral blood stem cell, bone marrow, or cord blood infusion.

Non-PBSC harvesting indications

- **Reduction in duration of neutropenia following cytotoxic chemotherapy when peripheral blood progenitor cells (PBSC) collection is NOT required, or**
- **After myeloablative therapy followed by bone marrow transplantation (Refer to individual protocol for start day)**

0.5 MU (5 microgram) / kg / day

Weight (kg)	Total dose calculated		No. Pre-Filled Syringes	
	0.5 MU / kg	Nearest MU dose	30 MU	48 MU
≤ 60	≤ 30	30	1	0
> 60 - 96	> 30 - 48	48	0	1
> 96 - 120	> 48 - 60	60	2	0
> 120 - 156	> 60 - 78	78	1	1

PBSC mobilization with Filgrastim alone or in combination with Plerixafor (for both myeloma and lymphoma patients)

1.0 MU (10 microgram) / kg / day

Weight (kg)	Total dose calculated		No. Pre-Filled Syringes	
	1.0 MU / kg	Nearest MU dose	30 MU	48 MU
≤ 48	≤ 48	48	0	1
> 48 - 60	> 48 - 60	60	2	0
> 60 - 78	> 60 - 78	78	1	1
> 78 - 90	> 78 - 90	90	3	0
> 90 - 96	> 90 - 96	96	0	2
> 96 - 108	> 96 - 108	108	2	1
> 108 - 126	> 108 - 126	126	1	2
> 126 - 144	> 126 - 144	144	0	3

NB. For collection of PBSC, if WCC ≥ 70 x 10^9/L, seek medical opinion to discuss dose prior to any administration decision.

LYMPHOMA (Autologous donors only) – dose following cytotoxic chemotherapy when PBSC collection is required (unlicensed dose)

1.0 MU (10 microgram) / kg / day

Weight (kg)	Total dose calculated		No. Pre-Filled Syringes	
	1.0 MU / kg	Nearest MU dose	30 MU	48 MU
≤ 48	≤ 48	48	0	1
> 48 - 60	> 48 - 60	60	2	0
> 60 - 78	> 60 - 78	78	1	1
> 78 - 90	> 78 - 90	90	3	0
> 90 - 96	> 90 - 96	96	0	2
> 96 - 108	> 96 - 108	108	2	1
> 108 - 126	> 108 - 126	126	1	2
> 126 - 144	> 126 - 144	144	0	3

NB. For collection of PBSC, if WCC ≥ 70 x 10^9/L, seek medical opinion to discuss dose prior to any administration decision.

MYELOMA (Autologous donors only)

First PBSC collection following cytotoxic chemotherapy

0.5 MU (5 microgram) / kg / day

Weight (kg)	Total dose calculated		No. Pre-Filled Syringes	
	0.5 MU / kg	Nearest MU dose	30 MU	48 MU
≤ 60	≤ 30	30	1	0
> 60 - 96	> 30 - 48	48	0	1
> 96 - 120	> 48 - 60	60	2	0
> 120 - 156	> 60 - 78	78	1	1

Second PBSC collection following cytotoxic chemotherapy

1.0 MU (10 microgram) / kg / day

Weight (kg)	Total dose calculated		No. Pre-Filled Syringes	
	1.0 MU / kg	Nearest MU dose	30 MU	48 MU
≤ 48	≤ 48	48	0	1
> 48 - 60	> 48 - 60	60	2	0
> 60 - 78	> 60 - 78	78	1	1
> 78 - 90	> 78 - 90	90	3	0
> 90 - 96	> 90 - 96	96	0	2
> 96 - 108	> 96 - 108	108	2	1
> 108 - 126	> 108 - 126	126	1	2
> 126 - 144	> 126 - 144	144	0	3

NB. For collection of PBSC, if WCC ≥ 70 x 10^9/L, seek medical opinion to discuss dose prior to any administration decision.

Dose Modifications – as per chemotherapy protocol.

Investigations – as per chemotherapy protocol.

Concurrent Medication – as per chemotherapy protocol.

Anti-emetic policy – as per chemotherapy protocol.

Adverse effects / regimen specific complications
For full exhaustive detailed descriptions, visit https://www.medicines.org.uk/emc/

Very commonly reported:

Headache, rash, musculoskeletal pain, fatigue, diarrhoea, vomiting, constipation, nausea, splenomegaly, hepatomegaly, thrombocytopenia, leukocytosis, anaemia, elevated blood uric acid,

elevated LDH.

- Filgrastim biosimilar should not be administered to patients with severe congenital neutropenia (Kostmann's syndrome) with abnormal cytogenetics
- Reports of GvHD and fatalities in patients receiving G-CSF after allogeneic BMT.
- Rare pulmonary adverse reactions, in particular interstitial pneumonia, pulmonary oedema reported after G-CSF administration. Patients with recent history of pulmonary infiltrates or pneumonia may be at higher risk. Onset of pulmonary signs, e.g. cough, fever and dyspnoea in association with radiological signs of pulmonary infiltrates and deterioration in pulmonary function may be preliminary signs of Adult Respiratory Distress Syndrome (ARDS). Filgrastim biosimilar should be discontinued and appropriate treatment given in these cases.
- Monitor bone density in patients with underlying osteoporotic bone diseases who undergo continuous therapy with filgrastim biosimilar for more than 6 months.
- Sickle cells crises, in some cases fatal, have been reported with filgrastim biosimilar in subjects with sickle cell disease. Caution in patients with sickle cell disease, and use only after careful evaluation of the potential risks and benefits.
- Cases of Sweet's Syndrome and cutaneous vasculitis had been reported.

References

1. Publicover A *et al*. Use of biosimilar granulocyte colony-stimulating factor for peripheral blood stem cell mobilization: an analysis of mobilization and engraftment. J Haematol. 2013 (162)107-111.
2. Amgen. Summary of Product Characteristics Neupogen. Updated 19/10/2015. Accessed via www.medicines.org.uk/emc on 18/04/2017.
3. Sandoz. Summary of Product Characteristics Zarzio. Updated 14/03/2016. Accessed via www.medicines.org.uk/emc on 18/04/2017.
4. Hospira. Summary of Product Characteristics Nivestim. Updated 16/11/2016. Accessed via www.medicines.org.uk/emc on 18/04/2017.
5. Accord. Summary of Product Characteristics Accofil. Updated 19/09/2016. Accessed via www.medicines.org.uk/emc on 18/04/2017.