



## Final Appraisal Recommendation

### Filgrastim (Nivestim<sup>®</sup>▼)

Submission by Hospira UK Ltd

Advice No: 0111 – February 2011

#### Recommendation of AWMSG

Filgrastim (Nivestim<sup>®</sup>▼) is recommended as an option for use within NHS Wales for the treatment of neutropenia:

- For the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy.
- For the mobilisation of peripheral blood progenitor cells (PBPC).
- In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of  $0.5 \times 10^9/l$  and a history of severe or recurrent infections, long term administration of filgrastim (Nivestim<sup>®</sup>▼) is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.
- For the treatment of persistent neutropenia (ANC less than or equal to  $0.5 \times 10^9/l$ ) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.
- Filgrastim (Nivestim<sup>®</sup>▼) is not suitable for shared care within NHS Wales for the above indication.
- Filgrastim (Nivestim<sup>®</sup>▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

Statement of use: No part of this recommendation may be used without the whole of the advice being quoted in full and should be cited as:

**Additional notes:**

Due to the potential differences between biosimilars from different manufacturers and/or the reference product (Nivestim<sup>®</sup>▼), post-marketing pharmacovigilance is essential and will be facilitated by the Risk Management Plan outlined in the Committee for Medicinal Products for Human Use assessment report.

Until studies have been performed to provide the required efficacy and safety data, the European group for blood and bone marrow transplantation (EBMT) does not recommend the use of biosimilar granulocyte-colony stimulating factors (G-CSFs) for mobilisation of stem cells in healthy donors for stem cell transplantation.

In reaching this recommendation AWMSG took account of the AWMSG Secretariat Assessment Report, the preliminary recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion, lay/patient/carer perspective and discussions at AWMSG.

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Filgrastim (Nivestim<sup>®</sup>▼) February 2011 v1.2 agreed AWMSG