filgrastim, 30 million units (300 microgram)/0.5mL and 48 million units (480 microgram)/0.8mL, prefilled syringe containing solution for injection or infusion (TevaGrastim®) (No: 629/10)

Teva UK Limited

Product Update

09 July 2010

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

filgrastim (TevaGrastim®) is accepted for use within NHS Scotland.

Indications under review:

- 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);
- 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;
- 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 $\leq$ 0.5 x 10^9/L, and a history of severe or recurrent infections, long term administration 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 1.0 x 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 (TevaGrastim®) is a follow on biosimilar product. It is manufactured at the same production site and is identical to the biosimilar product filgrastim (Ratiograstim®), previously accepted for use by SMC.

The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.

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Chairman Professor Kenneth R Paterson

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 12 May 2010.

Chairman
Scottish Medicines Consortium

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