



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Filgrastim and Lenograstim

June 3, 2014

Non-proprietary Name

- Filgrastim (genetical recombination) (including follow-on biologics/biosimilars)
- Lenograstim (genetical recombination)

Safety measure

Precautions section should be revised in a package insert.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added (underlined parts are revised):

Capillary leak syndrome:

Cases of capillary leak syndrome have been reported in patients treated with this drug. Patients should be carefully monitored, and hypotension, hypoalbuminaemia, oedema, pulmonary oedema, pleural effusion, ascites, haemoconcentration, and other signs and symptoms are observed, appropriate measures such as discontinuation of administration should be taken.