



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 (genetical recombination, follow-on biologics), pegfilgrastim (genetical recombination), and lenograstim (genetical recombination)

June 5, 2018

Non-proprietary name

Filgrastim (genetical recombination)

Filgrastim (genetical recombination, follow-on biologic 1)

Filgrastim (genetical recombination, follow-on biologic 2)

Filgrastim (genetical recombination, follow-on biologic 3)

Pegfilgrastim (genetical recombination)

Lenograstim (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Large vessel vasculitis (Inflammation in the aorta, common carotid artery, subclavian artery, or other large vessels):

Inflammation in large vessels may occur. If pyrexia, increased C-reactive protein (CRP), aortic wall hypertrophy, or other signs/symptoms are observed, appropriate measures, such

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as discontinuation of administration, should be taken.

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