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Translated by
Pharmaceuticals and Medical Devices Agency



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

Pegfilgrastim (genetical recombination)

March 31, 2020

Therapeutic category

Blood and body fluid agents-miscellaneous

Non-proprietary name

Pegfilgrastim (genetical recombination)

Safety measure

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Precautions should be revised in the package insert. Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

Current	Revision
Other Precautions (N/A)	Other Precautions <u>An increased risk of thrombocytopenia (a platelet count less than $5.0 \times 10^4/\mu\text{L}$) following administration of this drug has been reported in an epidemiological study conducted in Japan using a medical information database.</u>

Reference: Summary of MID-NET® study: A pharmacoepidemiological study on the association between G-CSF preparations and decreased platelet counts

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
15. OTHER PRECUTIONS 15.1 Information Based on Clinical Uses (N/A)	15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Uses <u>An increased risk of thrombocytopenia (a platelet count less than $5.0 \times 10^4/\mu\text{L}$) following administration of this drug has been reported in an epidemiological study conducted in Japan using a medical information database.</u>

Reference: Summary of MID-NET® study: A pharmacoepidemiological study on the association between G-CSF preparations and decreased platelet counts

N/A: Not Applicable, because the section is not included in the current package insert.

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