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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

Lenograstim (genetical recombination)

October 12, 2023

Therapeutic category

Other agents relating to blood and body fluids

Non-proprietary name

Lenograstim (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS <<u>Chemotherapy-induced neutropenia</u>> <u>An observational study performed overseas has reported an increased risk of myelodysplastic syndrome or acute myeloid leukemia in patients with breast or lung cancer who were treated with pegfilgrastim (genetical recombination) or filgrastim (genetical recombination), which are drugs of the same class, in conjunction with chemotherapy (monotherapy or combination therapy with radiotherapy). Although the causal relationship of this drug to myelodysplastic syndrome or acute myeloid leukemia is not clear, patients should be carefully monitored after administration of this drug.</u></p>

[Reference] Danese, M.D., et al.: Adv. Ther. 2022;39:2778-2795

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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