



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) Filgrastim (genetical recombination, biosimilar 1) Filgrastim (genetical recombination, biosimilar 2)

October 12, 2023

Therapeutic category

Other agents relating to blood and body fluids

Non-proprietary name

Filgrastim (genetical recombination)

Filgrastim (genetical recombination, biosimilar 1)

Filgrastim (genetical recombination, biosimilar 2)

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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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
<p>Important Precautions (N/A)</p>	<p>Important Precautions <u>Precautions for 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) 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.

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></p>

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	<p><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) 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>
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