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# Revision of PRECAUTIONS

## Pegfilgrastim (genetical recombination)
## Pegfilgrastim (genetical recombination, biosimilar 1)

October 12, 2023

### Therapeutic category

Other agents relating to blood and body fluids

### Non-proprietary name

Pegfilgrastim (genetical recombination)

Pegfilgrastim (genetical recombination, biosimilar 1)

### Safety measure

PRECAUTIONS should be revised.

**Pharmaceuticals and Medical Devices Agency**

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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 |
|---|---|
| 8. IMPORTANT PRECAUTIONS<br><Prevention of chemotherapy-induced febrile neutropenia><br>(N/A) | 8. IMPORTANT PRECAUTIONS<br><Prevention of chemotherapy-induced febrile neutropenia><br>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. |

[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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