



---

*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

## Nartograstim, Filgrastim, Lenograstim

September 13, 2016

### Non-proprietary name

- Nartograstim (genetical recombination)
- Filgrastim (genetical recombination)
- Filgrastim (genetical recombination) [filgrastim biosimilar 1]
- Filgrastim (genetical recombination) [filgrastim biosimilar2]
- Filgrastim (genetical recombination) [filgrastim biosimilar 3]
- Lenograstim (genetical recombination),

### Safety measure

Precautions should be revised in the package insert.

In the Important precautions section regarding anaphylaxis etc., the following text should be revised (underlined parts are revised):

Complete medical histories including histories of allergies and drug hypersensitivity should be taken before initiating the therapy with this drug to predict the response of hypersensitivity, etc.

In the Clinically significant adverse reaction subsection regarding shock of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Shock and anaphylaxis:

Shock and anaphylaxis may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be adopted.

**Pharmaceuticals and Medical Devices Agency**

Office of Safety I

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan

E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)