Revision of PRECAUTIONS

Nartograstim

June 3, 2014

Non-proprietary Name
Nartograstim (genetical recombination)

Safety measure
Precautions section should be revised in a package insert.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added (underlined parts are revised):

Capillary leak syndrome:
Cases of capillary leak syndrome have been reported in patients treated with other granulocyte colony-stimulating factors. Patients should be carefully monitored, and hypotension, hypoalbuminaemia, oedema, pulmonary oedema, pleural effusion, ascites, haemoconcentration, and other signs and symptoms are observed, appropriate measures such as discontinuation of administration should be taken.