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*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 Interferon beta-1b (genetical recombination)

January 10, 2017

## **Non-proprietary name**

Interferon beta-1b (genetical recombination)

## **Safety measure**

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Thrombotic thrombocytopenic purpura (TTP) and haemolytic uraemic syndrome (HUS):  
TPP (primary symptoms: thrombocytopenia, haemolytic anaemia with confirmed  
schistocytes, neuropsychological symptoms, pyrexia, and renal impairment) and HUS  
(primary symptoms: thrombocytopenia, haemolytic anaemia with confirmed schistocytes,  
and acute renal failure) may occur. Patients should be carefully monitored through periodic  
blood tests (platelet counts, red blood cell counts, etc.) and renal function tests, etc. If any  
abnormalities are observed, administration of this drug should be discontinued and  
appropriate measures should be adopted.