



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

Eftrenonacog alfa

(genetical recombination)

June 5, 2018

Non-proprietary name

Eftrenonacog alfa (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Adverse Reactions section, a Clinically Significant Adverse Reactions subsection should be newly added and the following language should be included (revised language is underlined):

Shock, anaphylaxis:

Shock or 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 taken.