



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

Pembrolizumab (genetical recombination)

February 12, 2019

Non-proprietary name

Pembrolizumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

The language concerning immune thrombocytopenic purpura, haemolytic anaemia, and pure red cell aplasia in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section should be revised as follows (revised language is underlined):

Serious blood disorder:

Serious blood disorder such as immune thrombocytopenic purpura, haemolytic anaemia, pure red cell aplasia, and agranulocytosis 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.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Haemophagocytic syndrome:

Haemophagocytic syndrome 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.