



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 Nivolumab (genetical recombination)

November 24, 2015

Non-proprietary name

Nivolumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

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

Type 1 diabetes mellitus:

Type 1 diabetes mellitus (including fulminant type 1 diabetes mellitus) may occur and cause diabetic ketoacidosis. Patients should be carefully monitored for symptoms such as thirst, nausea, and vomiting or increase in blood glucose levels. If type 1 diabetes mellitus is suspected, administration of this drug should be discontinued, and appropriate measures such as administration of insulin products should be adopted.