



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)

July 4, 2017

Non-proprietary name

Nivolumab (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 revised with regard to hepatic function disorder, hepatitis (underlined parts are revised):

Hepatic function disorder, hepatitis, sclerosing cholangitis:

Hepatic function disorder, hepatitis, and sclerosing cholangitis accompanied by increased levels of AST (GOT), ALT (GPT), γ -GTP, AI-P, and bilirubin, etc., may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures should be taken such as discontinuing administration of this drug.