



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)

April 19, 2018

Non-proprietary name

Pembrolizumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following language concerning hepatic impairment should be revised (revised language is underlined):

Hepatic impairment or sclerosing cholangitis accompanied by increased levels of certain hepatic enzymes, such as AST (GOT), ALT (GPT), γ -GTP, ALP, as well as bilirubin, may occur. Patients should be closely monitored through periodic liver function tests.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following language concerning hepatic impairment and hepatitis should be revised (revised language is underlined):

Hepatic impairment, hepatitis, sclerosing cholangitis:

Hepatic impairment, hepatitis, or sclerosing cholangitis accompanied by increased levels of certain hepatic enzymes, such as AST (GOT), ALT (GPT), γ -GTP, ALP, as well as bilirubin, may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures should be taken such as discontinuation of this drug.