



Revision of Precautions Pembrolizumab (genetical recombination)

April 20, 2017

Non-proprietary name

Pembrolizumab (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 added (underlined parts are revised):

Myocarditis: Myocarditis may occur. Chest pain, increased CK (CPK), electrocardiographic abnormality, etc. should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.