



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 Ipilimumab (genetical recombination)

January 11, 2018

Non-proprietary name

Ipilimumab (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):

Myositis:

Myositis may occur. Patients should be carefully monitored for muscular weakness, myalgia, and increase in CK (CPK), and if abnormalities are observed, appropriate measures should be taken such as discontinuing administration of this drug or administering a corticosteroid.