



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)

September 15, 2015

Non-proprietary name

Nivolumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

Various diseases or conditions may occur due to excessive immunoreaction caused by T cell activation effect of nivolumab. Patients should be carefully monitored. If any abnormalities are observed, appropriate differential diagnosis should be conducted taking into consideration that the adverse reaction may be caused by excessive immunoreaction. If adverse reaction due to excessive immunoreaction are suspected, appropriate measures such as administration of adrenal corticosteroids should be considered.

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

Myasthenia gravis and myositis:

Myasthenia gravis or myositis may occur, and there have been reports of cases where these complications have occurred. Muscular weakness, eyelid ptosis, dyspnoea, dysphagia, increased creatine kinase (creatine phosphokinase), etc. should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures such as administration of adrenal corticosteroids should be adopted. In addition, aggravation of respiratory conditions

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should be carefully monitored as respiratory failure may progress rapidly due to myasthenia gravis crisis.

Colitis and severe diarrhoea:

Colitis or severe diarrhoea may occur. Patients should be carefully monitored. If symptoms such as persistent diarrhoea, abdominal pain, and haematochezia are observed, appropriate measures such as discontinuation of administration should be adopted.