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Revision of Precautions
Nivolumab (genetical recombination)

October 18, 2016

Non-proprietary name

Nivolumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section with regard to excessive immunoreaction, 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. Serious adverse reactions may occur after discontinuation of treatment with nivolumab. The patient should continue to be carefully monitored even after discontinuation of treatment with nivolumab.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Immune thrombocytopenic purpura
Immune thrombocytopenic purpura may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of nivolumab should be discontinued and appropriate measures should be adopted.

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The following text with regard to myasthenia gravis and myositis should be revised (underlined parts are revised):

Myasthenia gravis, myocarditis, myositis, rhabdomyolysis

Myasthenia gravis, myocarditis, myositis, or rhabdomyolysis 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), abnormal electrocardiogram, and increased blood/urine myoglobin, etc. should be carefully monitored. If any abnormalities are observed, administration of nivolumab should be discontinued, and appropriate measures such as administration of adrenal corticosteroids should be adopted. In addition, aggravations of respiratory conditions should be carefully monitored as respiratory failure may progress rapidly due to the myasthenia gravis crisis.

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