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Revision of Precautions

Pembrolizumab（genetical recombination）

July 9, 2019

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Pembrolizumab（genetical recombination）

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse Reactions Clinically Significant Adverse Reactions Colitis, severe diarrhea: Since colitis and severe diarrhea may occur, patients should be carefully monitored. If symptoms such as persisted diarrhoea, abdominal pain, blood stool, etc. are observed, drug discontinuation or other appropriate measures should be taken.	Adverse Reactions Clinically Significant Adverse Reactions Colitis, enteritis, severe diarrhea: Colitis, enteritis, and severe diarrhea may occur, and cases of enterocolitis that resulted in perforation or ileus have been reported. Patients should be carefully monitored. If symptoms such as persisted diarrhoea, abdominal pain, blood stool, etc. are observed, drug discontinuation or other appropriate measures should be taken.

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