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Translated by
Pharmaceuticals and Medical Devices Agency



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)

July 9, 2019

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Nivolumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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
<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Colitis, severe diarrhea</p> <p><u>Since</u> colitis and severe diarrhea may occur, the patient should be carefully monitored. If symptoms such as persisted diarrhea, abdominal pain, blood stool, etc. are observed, drug discontinuation or other appropriate measures should be taken.</p>	<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Colitis, <u>enteritis</u>, severe diarrhea</p> <p>Colitis, <u>enteritis</u>, and severe diarrhea may occur, <u>and cases of enterocolitis that resulted in perforation or ileus have been reported.</u></p> <p>The patient should be carefully monitored. If symptoms such as persisted diarrhea, abdominal pain, blood stool, etc. are observed, drug discontinuation or other appropriate measures should be taken.</p>

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>Clinically Significant Adverse Reactions</p> <p>Colitis, severe diarrhea</p> <p>If symptoms such as persisted diarrhea, abdominal pain, blood stool, etc. are observed, drug discontinuation or other appropriate measures should be taken.</p>	<p>11. ADVERSE REACTIONS</p> <p>Clinically Significant Adverse Reactions</p> <p>Colitis, <u>enteritis</u>, severe diarrhea</p> <p><u>Cases of enterocolitis that resulted in perforation or ileus have been reported.</u> If symptoms such as persisted diarrhea, abdominal pain, blood stool, etc. are observed, drug discontinuation or other appropriate measures should be taken.</p>

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