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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)

November 5, 2020

Therapeutic category

Other antitumor agents

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, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>(N/A)</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Hepatic failure, hepatic impairment, hepatitis, and sclerosing cholangitis</p> <p>Hepatic failure, hepatic impairment accompanied by increased levels of AST, ALT, γ-GTP, AI-P as well as bilirubin, etc., hepatitis, and sclerosing cholangitis may occur.</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Fulminant hepatitis, hepatic failure, hepatic impairment, hepatitis, and sclerosing cholangitis may occur. Patients should be carefully monitored through periodic liver function tests.</u></p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Fulminant hepatitis</u>, hepatic failure, hepatic impairment, hepatitis, and sclerosing cholangitis</p> <p><u>Fulminant hepatitis</u>, hepatic failure, hepatic impairment accompanied by increased levels of AST, ALT, γ-GTP, AI-P as well as bilirubin, etc., hepatitis, and sclerosing cholangitis may occur.</p>

N/A: Not Applicable, because the section is not included in the current package insert.

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