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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

Pembrolizumab (genetical recombination)

June 15, 2021

Therapeutic category

Other antitumor agents

Non-proprietary name

Pembrolizumab (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. IMPORRANT PRECAUTIONS</p> <p>Hepatic impairment or sclerosing cholangitis may occur. Patients should be carefully monitored through periodical hepatic function tests (more frequently for co-administration with axitinib).</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Hepatic impairment, hepatitis, sclerosing cholangitis</p> <p>Hepatic impairment accompanied by elevated levels of AST, ALT, γ-GTP, Al-P, bilirubin, etc., hepatitis, or sclerosing cholangitis may occur.</p>	<p>8. IMPORRANT PRECAUTIONS</p> <p><u>Fulminant hepatitis, hepatic failure,</u> hepatic impairments, or sclerosing cholangitis may occur. Patients should be carefully monitored through periodical hepatic function tests (more frequently for co-administration with axitinib).</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Fulminant hepatitis, hepatic failure,</u> hepatic impairment, hepatitis, sclerosing cholangitis</p> <p><u>Fulminant hepatitis, hepatic failure,</u> hepatic impairment accompanied by elevated levels of AST, ALT, γ-GTP, Al-P, bilirubin, etc., hepatitis, or sclerosing cholangitis may occur.</p>

N/A: Not Applicable. No corresponding language is included in the current package insert.

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