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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

Atezolizumab (genetical recombination)

November 16, 2021

Therapeutic category

Other antitumor agents

Non-proprietary name

Atezolizumab (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 Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p><common to all indications></p> <p>Hepatic impairment may occur. Liver function tests should be performed prior to and periodically during administration of this drug, and patients should be carefully monitored for their conditions.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Hepatic impairment, hepatitis</p> <p>Hepatic impairment accompanied by increased levels of AST, ALT, Al-P, γ-GTP as well as bilirubin, etc., and hepatitis may occur.</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><common to all indications></p> <p>Hepatic impairment <u>and sclerosing cholangitis</u> may occur. Liver function tests should be performed prior to and periodically during administration of this drug, and patients should be carefully monitored for their conditions.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Hepatic impairment, hepatitis, <u>sclerosing cholangitis</u></p> <p>Hepatic impairment accompanied by increased levels of AST, ALT, Al-P, γ-GTP as well as bilirubin, etc., hepatitis, <u>and sclerosing cholangitis</u> may occur.</p>

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