

*This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.*

*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

## Avelumab (genetical recombination)

July 30, 2025

### **Therapeutic category**

Other antitumor agents

### **Non-proprietary name**

Avelumab (genetical recombination)

### **Safety measure**

PRECAUTIONS should be revised.

*This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.*

*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.*

Revised language is underlined.

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