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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 24, 2023

Therapeutic category

Other antitumor agents

Non-proprietary name

Nivolumab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><Unresectable, advanced or recurrent non-small cell lung cancer></p> <p>When this drug is co-administered with other antineoplastic drugs, the other antineoplastic drugs to be administered should be selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section and with consideration for the incidence of PD-L1 expression in the patients investigated in the clinical studies.</p> <p><Neoadjuvant therapy for non-small cell lung cancer></p> <p>Other antineoplastic drugs to be administered should be selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section.</p> <p><Unresectable, advanced or recurrent gastric cancer></p> <p>When this drug is co-administered with other antineoplastic drugs, the other antineoplastic drugs to be administered should be</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><Unresectable, advanced or recurrent non-small cell lung cancer></p> <p>When this drug is co-administered with other antineoplastic drugs, the other antineoplastic drugs to be administered should be selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section and <u>with reference to the latest Japanese and overseas guidelines or other relevant sources as well as</u> with consideration for the incidence of PD-L1 expression in the patients investigated in the clinical studies.</p> <p><Neoadjuvant therapy for non-small cell lung cancer></p> <p>Other antineoplastic drugs to be administered should be selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section <u>and with reference to the latest Japanese and overseas guidelines or other relevant sources.</u></p> <p><Unresectable, advanced or recurrent gastric cancer></p> <p>When this drug is co-administered with other antineoplastic drugs, the other antineoplastic drugs to be administered should be</p>

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<p>selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section.</p> <p><Radically unresectable, advanced or recurrent oesophageal carcinoma></p> <p>When this drug is co-administered with other antineoplastic drugs, the other antineoplastic drugs to be administered should be selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section.</p>	<p>selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section <u>and with reference to the latest Japanese and overseas guidelines or other relevant sources.</u></p> <p><Radically unresectable, advanced or recurrent oesophageal carcinoma></p> <p>When this drug is co-administered with other antineoplastic drugs, the other antineoplastic drugs to be administered should be selected with sufficient understanding of the contents of the 17.CLINICAL STUDIES section <u>and with reference to the latest Japanese and overseas guidelines or other relevant sources.</u></p>
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