



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. The PMDA shall not be responsible for any consequences resulting from the use of this English version.

Revision of PRECAUTIONS

Pembrolizumab (genetical recombination)

May 17, 2024

Therapeutic category

Other antitumor agents

Non-proprietary name

Pembrolizumab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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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 a thorough understanding of the contents of the 17. CLINICAL STUDIES section.</p> <p><Recurrent or metastatic head and neck cancer></p> <p>Dosage and administration of this drug should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section and with full understanding of efficacy and safety of this drug.</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 a thorough 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><Recurrent or metastatic head and neck cancer></p> <p>Dosage and administration of this drug should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section and with full understanding of efficacy and safety of this drug.</p> <p><u>In addition, when this drug is co-administered with other antineoplastic drugs, the other antineoplastic drugs to be administered should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section and with reference to the latest Japanese and overseas guidelines or other relevant sources.</u></p>

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<p><Radically unresectable or metastatic renal cell carcinoma></p> <p>Other antineoplastic drugs to be co-administered should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section.</p> <p><PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer></p> <p>Other antineoplastic drugs to be co-administered should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section.</p> <p><Pre- and postoperative adjuvant therapy for hormone receptor-negative and HER2-negative breast cancer at high risk of recurrence></p> <p>Dosage and administration of this drug, <u>as well as other antineoplastic drugs to be co-administered</u>, should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section.</p>	<p><Radically unresectable or metastatic renal cell carcinoma></p> <p>Other antineoplastic drugs to be co-administered should be selected with a thorough 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><PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer></p> <p>Other antineoplastic drugs to be co-administered should be selected with a thorough 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><Pre- and postoperative adjuvant therapy for hormone receptor-negative and HER2-negative breast cancer at high risk of recurrence></p> <p>Dosage and administration of this drug should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section.</p> <p><u>In addition, other antineoplastic drugs to be co-administered should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section and with reference to the latest Japanese and overseas guidelines or other relevant sources</u>.</p>
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<p><Unresectable, advanced or recurrent gastric cancer></p> <p>Other antineoplastic drugs to be co-administered should be selected with a thorough understanding of the contents of the 17. CLINICAL STUDIES section.</p>	<p><Unresectable, advanced or recurrent gastric cancer></p> <p>Other antineoplastic drugs to be co-administered should be selected with a thorough 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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