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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

Cetuximab sarotalocan sodium (genetical recombination)

June 14, 2022

Therapeutic category

Other antitumor agents

Non-proprietary name

Cetuximab sarotalocan sodium (genetical recombination)

Safety measure

Precautions should be revised.

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>(N/A)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with complication or history of diseases, etc.</p> <p>(N/A)</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> | <p>8. IMPORTANT PRECAUTIONS</p> <p><u>Fistula, mucocutaneous ulceration or necrosis may occur at the site of laser irradiation. Whether a tumour invasion into the skin or mucous membrane has occurred should be adequately confirmed prior to the administration of this drug. In addition, during the treatment with this drug, the patient's condition including the presence or absence of fistula, ulceration or necrosis should be adequately monitored.</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with complication or history of diseases, etc.</p> <p><u>Patients with tumour invasion into the skin or mucous membrane</u> <u>In patients with tumour invasion into the skin or mucous membrane, the effectiveness and risks of this drug should be carefully considered prior to deciding whether or not to treat with this drug.</u> <u>Fistula, mucocutaneous ulceration or necrosis may occur at the site of laser irradiation.</u></p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> |

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| (N/A) | <u>Fistula, mucocutaneous ulceration or necrosis</u> <u>Fistula, skin ulceration, mucosal ulceration, skin necrosis, or</u> <u>mucosal necrosis may occur at the site of laser irradiation.</u> |
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N/A: Not Applicable. No corresponding language is included in the current Precautions.

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