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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Cetuximab (genetical recombination)

March 30, 2021

Therapeutic category

Other antitumor agents

Non-proprietary name

Cetuximab (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 Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Hypomagnesaemia Hypomagnesaemia accompanied by symptoms such as prolonged QT, convulsion, numbness, or general malaise may occur. Caution should be exercised for hypocalcaemia, hypokalaemia or other electrolyte abnormalities caused by hypomagnesaemia, which may particularly exacerbate the symptoms of hypomagnesaemia. Appropriate measures should be taken such as electrolyte replacement as necessary if electrolyte abnormalities are observed.

N/A: Not Applicable. No corresponding language is included in the current package insert.

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