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Pharmaceuticals and Medical Devices Agency

Revision of PRECAUTIONS

Linezolid

February 15, 2024

Therapeutic category

Synthetic antibacterials

Non-proprietary name

Linezolid

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director-General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Rhabdomyolysis:</u> <u>Rhabdomyolysis may occur. Patients should be carefully monitored. If myalgia, feelings of weakness, increased CK (CPK), increased blood myoglobin, increased urine myoglobin, etc. occur, administration of this drug should be discontinued and appropriate measures should be taken. In addition, patients should be carefully monitored for signs of acute kidney injury due to rhabdomyolysis.</u>

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

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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Rhabdomyolysis</u> <u>If myalgia, feelings of weakness, increased CK, increased blood myoglobin, increased urine myoglobin, etc. occur, administration of this drug should be discontinued and appropriate</u>

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