



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

Linezolid

Aug 6, 2014

Non-proprietary Name

Linezolid

Safety measure

Precautions should be revised in the package inserts.

- In Important Precautions section, the following texts should be added:
Metabolic acidosis including lactic acidosis may occur. Patients should be adequately advised to visit their doctor immediately if nausea and/or vomiting repeatedly occur. If these symptoms are observed or if signs and symptoms such as unexplained acidosis and/or decreased blood bicarbonate are observed, appropriate measures such as discontinuation of administration should be taken.
- In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added:

Metabolic acidosis:

Metabolic acidosis including lactic acidosis may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

Hepatic dysfunction:

Hepatic dysfunction with elevations of aspartate aminotransferase (glutamate oxaloacetate transaminase), alanine aminotransferase (glutamate pyruvate transaminase), lactate dehydrogenase, alkaline phosphatase, and/or γ -glutamyl transpeptidase may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.