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.