Revision of Precautions

Linagliptin

January 9, 2015

Non-proprietary Name
linagliptin

Safety measure
Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added (underlined parts are revised):

Hepatic dysfunction:
Hepatic dysfunction with elevations of aspartate aminotransferase (glutamate oxaloacetate transaminase) and alanine aminotransferase (glutamate pyruvate transaminase) may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.