



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

teneligliptin hydrobromide hydrate

October 21, 2014

Non-proprietary Name

teneligliptin hydrobromide hydrate

Safety measure

Precautions should be revised in the package insert.

In Clinically significant adverse reactions subsection of 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), alanine aminotransferase (glutamate pyruvate transaminase), etc. may occur.

Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

Interstitial pneumonia:

Interstitial pneumonia may occur. If cough, dyspnoea, pyrexia, abnormal chest sound (crepitations), etc. are observed, examinations including chest X-ray, chest CT scan, and serum marker test should be performed immediately. If interstitial pneumonia is suspected, administration of this drug should be discontinued, and appropriate measures including administration of corticosteroids should be taken.