



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, teneligliptin hydrobromide hydrate/canagliflozin hydrate, and linagliptin

March 20, 2018

Non-proprietary name

Teneligliptin hydrobromide hydrate

Teneligliptin hydrobromide hydrate/canagliflozin hydrate

Linagliptin

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following language should be added (revised language is underlined):

Acute pancreatitis may occur. Patients should be instructed to consult with a physician immediately if initial symptoms including persistent and intense abdominal pain and/or vomiting occur.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

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Acute pancreatitis:

Acute pancreatitis may occur. Patients should be carefully monitored. If any abnormalities, including persistent and intense abdominal pain and/or vomiting are observed, administration of this drug should be discontinued and appropriate measures should be taken.

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