



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

Tofogliflozin hydrate

January 9, 2015

Non-proprietary Name

tofogliflozin hydrate

Safety measure

Precautions should be revised in the package insert.

In the Careful administration section, the following texts should be added (underlined parts are revised):

Patients who are susceptible to dehydration (ex. patients with poor blood glucose control, geriatric patients, and patients who are concomitantly administered diuretics)

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

Dehydration:

Dehydration may occur. Patients should be advised on appropriate water intake and carefully monitored. If symptoms including thirst, polyuria, pollakiuria, and decreased blood pressure are observed and dehydration is suspected, appropriate measures such as drug suspension and fluid replacement should be taken. Careful attention should be exercised because cases of dehydration followed by thromboembolism including cerebral infarction and other diseases have been reported.

Pyelonephritis:

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