



Summary of investigation results

Tofogliflozin hydrate

January 9, 2015

Non-proprietary Name

tofogliflozin hydrate

Brand Name (Marketing Authorization Holder)

Apleway Tablets 20 mg (Sanofi K.K.) and Deberza Tablets 20 mg (Kowa Company, Ltd.)

Indications

Type 2 diabetes mellitus

Summary of revision

'Pyelonephritis' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of pyelonephritis have been reported in patients treated with tofogliflozin hydrate in Japan. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package inserts was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 6 cases of adverse events suggestive of pyelonephritis have been reported (including 2 cases in which causality could not be ruled out). No fatal cases have been reported.