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.

Summary of investigation results

teneligliptin hydrobromide hydrate

October 21, 2014

Non-proprietary Name
teneligliptin hydrobromide hydrate

Brand Name (Marketing Authorization Holder)
Tenelia Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation)

Indications
Type 2 diabetes mellitus

Summary of revision
The following should be added in Clinically significant adverse reactions section:

- Hepatic dysfunction
- Interstitial pneumonia

Background of the revision and investigation results
Cases of hepatic dysfunction and/or interstitial pneumonia have been reported in patients treated with teneligliptin hydrobromide hydrate in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan
A total of 6 cases associated with hepatic dysfunction has been reported (including 3 cases in which causality could not be ruled out). Of the 6 cases, a fatality has been reported. No causal relationship with teneligliptin hydrobromide hydrate was established in the fatal case.

A total of 6 cases associated with interstitial pneumonia has been reported (including 4 cases in which causality could not be ruled out). Of the 6 cases, no fatalities have been reported.

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