This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Linagliptin

January 9, 2015

Non-proprietary Name
linagliptin

Brand Name (Marketing Authorization Holder)
Trazenta Tablets 5 mg (Nippon Boehringer Ingelheim Co., Ltd.)

Indications
Type 2 diabetes mellitus

Summary of revision
'Hepatic dysfunction' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results
Cases of hepatic dysfunction have been reported in patients treated with linagliptin in Japan. Following an investigation result 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 9 cases of adverse events suggestive of hepatic dysfunction have been reported (including 5 cases in which causality could not be ruled out). A fatality has been reported. No causal relationship with linagliptin was established in the fatal case.

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