



Summary of investigation results

Linagliptin

October 17, 2017

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

“Interstitial pneumonia” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of interstitial pneumonia have been reported in patients treated with linagliptin in Japan. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan (in and after 2014)

A total of 20 cases associated with interstitial pneumonia have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.