



Summary of Investigation Results

Omarigliptin, trelagliptin succinate, saxagliptin hydrate

April 19, 2018

Non-proprietary name

- a. Omarigliptin
- b. Trelagliptin succinate
- c. Saxagliptin hydrate

Brand name (Marketing authorization holder)

- a. Marizev Tablets 12.5 mg, 25 mg (MSD K.K.)
- b. Zafatek Tablets 50 mg, 100 mg (Takeda Pharmaceutical Co., Ltd.)
- c. Onglyza Tablets 2.5 mg, 5 mg (Kyowa Hakko Kirin Co., Ltd.)

Indications

Type 2 diabetes mellitus

Summary of revision

“Pemphigoid” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of pemphigoid have been reported in patients treated with omarigliptin, trelagliptin succinate, or saxagliptin hydrate in Japan. Based on the results of their investigation of the evidence currently available and in consultation with expert advisors, MHLW/PMDA concluded that revision of the package insert was necessary.



Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

- a. A total of 8 cases associated with pemphigoid have been reported to date (including 3 cases for which a causal relationship with the product could not be ruled out.) No patient mortalities have been reported to date.
- b. A total of 7 cases associated with pemphigoid have been reported to date (including 1 case for which a causal relationship with the product could not be ruled out.) No patient mortalities have been reported to date.
- c. A total of 4 cases associated with pemphigoid have been reported to date (including 2 cases for which a causal relationship with the product could not be ruled out.) No patient mortalities have been reported to date.