



Summary of investigation results

Anagliptin, linagliptin, teneligliptin hydrobromide hydrate, and teneligliptin hydrobromide hydrate/canagliflozin hydrate

March 20, 2018

Non-proprietary name

- a. Anagliptin
- b. Linagliptin
- c. Teneligliptin hydrobromide hydrate
- d. Teneligliptin hydrobromide hydrate/canagliflozin hydrate

Brand name (Marketing authorization holder)

- a. Suiny Tab. 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)
- b. Trazenta Tablets 5 mg (Nippon Boehringer Ingelheim Co., Ltd.)
- c. Tenelia Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation.)
- d. Canalia Combination Tablets (Mitsubishi Tanabe Pharma Corporation.)

Indications

Type 2 diabetes mellitus

Summary of revision

Precautions regarding acute pancreatitis should be added to the Important Precautions section.

“Acute pancreatitis” should be added to the Clinically Significant Adverse Reactions

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section.

Investigation results and background of the revision

Cases of acute pancreatitis have been reported in patients treated with anagliptin, linagliptin, or teneligliptin hydrobromide hydrate in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the evidence currently available and as a result of consultation with expert advisors.

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

- a. A total of 4 cases associated with acute pancreatitis have been reported (including 2 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 19 cases associated with acute pancreatitis have been reported (including 5 cases 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 9 cases associated with acute pancreatitis have been reported (including 4 cases for which a causal relationship with the product could not be ruled out). No patient mortalities have been reported to date.
- d. No cases associated with acute pancreatitis have been reported to date.