



Summary of investigation results

Anagliptin

July 7, 2015

Non-proprietary name

Anagliptin

Brand name (Marketing authorization holder)

Suiny Tablets 100 mg (Sanwa kagaku kenkyusho Co. Ltd.)

Indications

Type 2 diabetes mellitus

To be used only when the patients do not sufficiently respond to one of the following treatments:

- a. Diet and exercise therapies alone
- b. Alpha-glucosidase inhibitor along with diet and exercise therapies
- c. Biguanide along with diet and exercise therapies
- d. Sulfonylurea along with diet and exercise therapies
- e. Thiazolidinedione along with diet and exercise therapies

Summary of revision

1. 'Patients who have a history of abdominal surgery or intestinal obstruction' should be newly added to the Careful administration section.
2. 'Intestinal obstruction' should be newly added to the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases associated with intestinal obstruction have been reported in patients treated with anagliptin in Japan. Following an investigation result based on the opinions of expert



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.

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

A total of 3 cases associated with intestinal obstruction have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). Of the 3 cases, no fatality has been reported.