



Summary of investigation results

Sitagliptin phosphate hydrate

March 24, 2015

Non-proprietary name

Sitagliptin phosphate hydrate

Brand name (Marketing authorization holder)

Glactiv Tablets 12.5 mg, 25 mg, 50 mg, and 100 mg (Ono Pharmaceutical Co., Ltd.) and
Januvia Tablets 12.5 mg, 25 mg, 50 mg, and 100 mg (MSD K.K.)

Indications

Type 2 diabetes mellitus

Summary of revision

‘Thrombocytopenia’ should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of adverse events of thrombocytopenia have been reported in patients treated with sitagliptin phosphate hydrate in Japan. Following an investigation based on the opinions of expert advisors and 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 6 cases of adverse events of thrombocytopenia have been reported (including 2 cases in which causality could not be ruled out). No fatalities have been reported.