



Summary of investigation results

Peramivir hydrate

October 18, 2016

Non-proprietary name

Peramivir hydrate

Brand name (Marketing authorization holder)

Rapiacta 300 mg Bag for Intravenous Drip Infusion, Rapiacta 150 mg Vial for Intravenous Drip Infusion (Shionogi & Co., Ltd.)

Indications

Influenza A or B virus infection

Summary of revision

“Acute renal failure” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of acute renal failure have been reported in Japan. Following an investigation result 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

A total of 7 cases associated with acute renal failure has been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.