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.

Summary of investigation results

Peramivir hydrate

April 21, 2016

Non-proprietary name

Peramivir hydrate

Brand name (Marketing authorization holder)

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

Indications

Type A or B influenza virus infection

Summary of revision

1. Precautions regarding “shock and anaphylaxis” should be newly added in the Important Precautions section.
2. “Anaphylaxis” should be added to the “Shock” subsection in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of anaphylaxis have been reported in patients treated with peramivir hydrate 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 17 cases associated with anaphylaxis have been reported (including 8 cases for which a causal relationship to the product could not be ruled out). Of the 17 cases, 1 fatal

case has been reported (a causal relationship between the product and the fatal outcome could not be ruled out for this patient).

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