



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

## Revision of Precautions Peramivir hydrate

April 21, 2016

## Non-proprietary name

Peramivir hydrate

## Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

Shock and anaphylaxis may occur. During the administration, patients should be carefully monitored under the conditions where emergency treatment is available.

Shock and anaphylaxis may occur even after discontinuation of administration, and therefore, caution should be exercised.

In the Clinically significant adverse reaction subsection regarding shock of the Adverse reaction section, the following text should be revised (underlined parts are revised):

## Shock and anaphylaxis:

Shock <u>and anaphylaxis</u> (decreased blood pressure, facial pallor, cold sweat, <u>dyspnea</u>, <u>urticarial</u>, etc.) may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be adopted.

\* Peramivir hydrate is designated as a drug requiring preparation of a Drug Guide for Patients.