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

Famciclovir

November 22, 2016

Non-proprietary name

Famciclovir

Brand name (Marketing authorization holder)

Famvir Tablets 250 mg (Asahi Kasei Pharma Corporation)

Indications

Herpes simplex

Herpes zoster

Summary of revision

“Shock, anaphylaxis” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of shock or anaphylaxis have been reported in patients treated with famciclovir both in Japan and overseas. In addition, the company core datasheet (CCDS)* has been revised. 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 3 cases associated with shock or anaphylaxis have been reported (including 3 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

NOTE:

* CCDS is prepared by the marketing authorization holder and covers materials relating to

safety, indications, dosing, pharmacology, and other information concerning the product.

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