



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 Sitafloxacin hydrate

August 4, 2016

Non-proprietary name

Sitafloxacin hydrate

Safety measure

Precautions should be revised in the package insert.

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

Thrombocytopenia: Thrombocytopenia 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.

Psychiatric symptoms including confusion, delirium, and hallucination: Psychiatric symptoms including confusion, delirium, and hallucination 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.

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