



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

Tosufloxacin tosilate hydrate (for oral use)

April 19, 2018

Non-proprietary name

Tosufloxacin tosilate hydrate (for oral use)

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following language concerning acute kidney injury and interstitial nephritis should be revised (revised language is underlined):

Acute kidney injury, interstitial nephritis, nephrogenic diabetes insipidus:

Serious renal impairments such as acute kidney injury, interstitial nephritis, or nephrogenic diabetes insipidus may occur. Patients should be carefully monitored through methods such as periodic examinations. If any abnormalities are observed, this drug should be discontinued and appropriate measures should be taken.

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