



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

Ciprofloxacin hydrochloride hydrate

Tosufloxacin tosilate hydrate

(oral preparations without dosage and administration for pediatric use)

Norfloxacin (oral dosage form)

Prulifloxacin

January 10, 2019

Non-proprietary name

Sitafloxacin hydrate, ciprofloxacin hydrochloride hydrate, tosufloxacin tosilate hydrate (tablets for adults), norfloxacin (oral dosage form), prulifloxacin

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Careful Administration section (revised language is underlined):

Patients complicated with aortic aneurysm or aortic dissection, or patients who have a previous history, a family history, or risk factors (Marfan's syndrome, etc.) of aortic

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aneurysm or aortic dissection

An Important Precautions section should be newly added and the following language should be included (revised language is underlined):

Aortic aneurysm or aortic dissection may occur. Patients should be carefully monitored and instructed to seek medical attention immediately if they experience symptoms such as pain in the abdomen, chest, or back. Imaging assessment should be considered if necessary for patients complicated with aortic aneurysm or aortic dissection, or patients who have a previous history, a family history, or risk factors of aortic aneurysm or aortic dissection.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions Section (revised language is underlined):

Aortic aneurysm, aortic dissection:

Aortic aneurysm or aortic dissection may occur. If any abnormalities are observed, appropriate measures should be taken.

* Ciprofloxacin hydrochloride hydrate, norfloxacin (oral dosage form), and prulifloxacin are designated as drugs requiring preparation of a Drug Guide for Patients.