



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

Ofloxacin (oral dosage form)

Garenoxacin mesilate hydrate

Ciprofloxacin

Tosufloxacin tosilate hydrate

(oral preparations with dosage and administration for pediatric use)

Pazufloxacin mesilate

Moxifloxacin hydrochloride

(oral dosage form)

Levofloxacin hydrate

(oral and injectable dosage forms)

Lomefloxacin hydrochloride

(oral dosage form)

January 10, 2019

Pharmaceuticals and Medical Devices Agency

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Non-proprietary name

Ofloxacin (oral dosage form), garenoxacin mesilate hydrate, ciprofloxacin, tosufloxacin tosilate hydrate (tablets and fine granules for pediatric), pazufloxacin mesilate, moxifloxacin hydrochloride (oral dosage form), levofloxacin hydrate (oral and injectable dosage forms), lomefloxacin hydrochloride (oral dosage form)

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 aneurysm or aortic dissection

The following language should be added to the Important Precautions section (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.

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

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