Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Lomefloxacin hydrochloride (oral dosage form)

September 24, 2019

Therapeutic category

Synthetic antibiotics

Non-proprietary name

Lomefloxacin hydrochloride

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse Reactions Clinically Significant Adverse Reactions Tendon disorders such as Achilles tendonitis and tendon rupture: It has been reported that tendon disorders such as Achilles tendonitis and tendon rupture occurred in patients treated with this drug. Patients should be carefully monitored and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken. (N/A)	Adverse Reactions Clinically Significant Adverse Reactions Tendon disorders such as Achilles tendonitis and tendon rupture: Tendon disorders such as Achilles tendonitis and tendon rupture may occur. If symptoms such as pain, edema, and redness around the tendon are observed, administration of this drug should be discontinued and appropriate measures should be taken. Psychiatric symptoms: Psychiatric symptoms such as hallucination and delirium may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

N/A: Not Applicable, because the section is not included in the current package insert.

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