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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Levofloxacin hydrate (oral, injectable dosage forms)

September 24, 2019

Therapeutic category

Synthetic antibiotics

Non-proprietary name

Levofloxacin hydrate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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: Tendon disorders such as Achilles tendonitis and tendon rupture may occur. If symptoms such as pain and edema around the tendon are observed, administration of this drug should be discontinued and appropriate measures should be taken. These tendon disorders are more likely to occur in patients aged 60 years or older, patients who concomitantly use corticosteroids, and patients with a history of organ transplant. (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. These tendon disorders are more likely to occur in patients with a history of organ transplant. Peripheral neuropathy: Peripheral neuropathy may occur. If symptoms such as numbness, muscle weakness, or pain 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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