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Translated by
Pharmaceuticals and Medical Devices Agency



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)

September 24, 2019

Therapeutic category

Synthetic antibiotics

Non-proprietary name

Ofloxacin

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

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

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