

Published by  
Ministry of Health, Labour and Welfare



Translated by  
Pharmaceuticals and Medical Devices Agency



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*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

## Tosufloxacin tosilate hydrate (oral dosage form)

September 24, 2019

### **Therapeutic category**

Synthetic antibiotics

### **Non-proprietary name**

Tosufloxacin tosilate hydrate

### **Safety measure**

Precautions should be revised in the package insert.

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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
<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p><u>Peripheral neuropathy:</u></p> <p><u>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.</u></p> <p><u>Tendon disorders such as Achilles tendonitis and tendon rupture:</u></p> <p><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></p> <p><u>Psychiatric symptoms:</u></p> <p><u>Psychiatric symptoms such as hallucination and delirium may occur. Patients should be carefully monitored and if any abnormalities 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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