

*This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.*

*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)

November 26, 2025

### **Therapeutic category**

Synthetic antibacterials

### **Non-proprietary name**

Tosufloxacin tosilate hydrate (oral dosage form)

### **Safety measure**

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Acute kidney injury, nephritis interstitial, nephrogenic diabetes insipidus</p> <p>Serious renal disorders including acute kidney injury, nephritis interstitial, and nephrogenic diabetes insipidus may occur.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Acute kidney injury, nephritis interstitial, nephrogenic diabetes insipidus, <u>calculus urinary</u></p> <p>Serious renal disorders including acute kidney injury, nephritis interstitial, and nephrogenic diabetes insipidus may occur.</p> <p><u>In addition, crystalluria containing this drug as a component may occur and cause acute kidney injury and calculus urinary. This condition has been reported especially more frequently in children.</u></p>