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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

## Aciclovir (oral and injectable dosage forms)

## Valaciclovir hydrochloride

March 31, 2020

### **Therapeutic category**

Antivirals

### **Non-proprietary name**

Aciclovir (oral and injectable dosage forms), valaciclovir hydrochloride

### **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
Adverse Reactions Clinically Significant Adverse Reactions Acute renal failure	Adverse Reactions Clinically Significant Adverse Reactions Acute renal failure, <u>tubulointerstitial nephritis</u>

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions Acute kidney injury	11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions Acute kidney injury, <u>tubulointerstitial nephritis</u>

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