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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

## Vonoprazan fumarate

October 6, 2020

### **Therapeutic category**

Agents for peptic ulcer

### **Non-proprietary name**

Vonoprazan fumarate

### **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, 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 <Common to all indications> (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <Common to all indications> <u>Shock, anaphylaxis</u>  <u>Hepatic impairment</u>

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

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