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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

## Ensirelvir fumaric acid

July 20, 2023

### **Therapeutic category**

Anti-virus agents

### **Non-proprietary name**

Ensirelvir fumaric acid

### **Safety measure**

PRECAUTIONS should be revised.

**Pharmaceuticals and Medical Devices Agency**

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS (N/A)	11. ADVERSE REACTIONS <u>11.1 Clinically Significant Adverse Reactions</u> <u>Anaphylaxis</u>

(N/A) Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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