

*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

## Ensitrelvir fumaric acid

December 17, 2024

### **Therapeutic category**

Anti-virus agents

### **Non-proprietary name**

Ensitrelvir fumaric acid

### **Safety measure**

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS  (N/A)	8. IMPORTANT PRECAUTIONS  <u>The necessity of administering this drug to women of childbearing potential should be carefully considered. If administration is deemed necessary, attention should be paid to the following points.</u>  <u>Prior to administering this drug, the absence of pregnancy and the absence of the possibility of pregnancy should be confirmed through sufficient patient interviews.</u>  <u>The following should be explained to patients before starting administration of this drug:</u>  <u>•This drug can cause foetal harm when administered to a pregnant woman.</u>  <u>•If pregnancy is detected or suspected during administration of this drug, this drug should be discontinued immediately.</u>  <u>•If pregnancy is detected or suspected during administration of this drug or within 2 weeks after the last administration of this drug, a physician, pharmacist, etc. should be consulted promptly.</u>

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