

*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

## Sunitinib malate

July 30, 2025

### **Therapeutic category**

Other antitumor agents

### **Non-proprietary name**

Sunitinib malate

### **Safety measure**

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Hyperammonaemia</u> <u>Hyperammonaemia may occur even in the absence of abnormal</u> <u>hepatic function. If disturbed consciousness is observed,</u> <u>measurement of blood ammonia levels should be considered.</u>

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