独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Sunitinib malate

July 30, 2025

Non-proprietary name

Sunitinib malate

Brand name (marketing authorization holder)

Sutent Capsule 12.5 mg (Pfizer Japan Inc.) and the others

Japanese market launch

June 2008

Indications

•Imatinib-resistant gastrointestinal stromal tumour

•Radically unresectable or metastatic renal cell carcinoma

•Pancreatic neuroendocrine tumour

Summary of revisions

“Hyperammonaemia” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving hyperammonaemia were evaluated. Cases of hyperammonaemia not accompanied by abnormal hepatic function were identified, and those for which a causal relationship to sunitinib malate was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

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Reference: Number of cases* and patient mortalities involving hyperammonaemia reported in Japan and overseas

A total of 7 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and the event was reasonably possible).
One instance of patient mortality has been reported in Japan to date. (A causal relationship between the drug and the death following the event could not be established for this case.)

A total of 13 cases have been reported overseas to date (including 2 cases for which a causal relationship between the drug and the event was reasonably possible).
One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and the death following the event could not be established for this case.)

*Cases collected in the PMDA's safety database for drugs

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).