FIRST TIME GENERIC APPROVAL

Brand Name	Sunitinib malate
Generic Name	sunitinib malate
Drug Manufacturer	Sun Pharmaceutical Industries Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

August 16, 2021

LAUNCH DATE

N/A

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 213914

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Sunitinib malate capsules are a kinase inhibitor indicated for:

- treatment of adult patients with gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate.
- treatment of adult patients with advanced renal cell carcinoma (RCC).
- adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy.
  treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease.

MECHANISMS OF ACTION

Sunitinib is a small molecule that inhibits multiple receptor tyrosine kinases (RTKs), some of which are implicated in tumor growth, pathologic angiogenesis, and metastatic progression of cancer. sunitinib was evaluated for its inhibitory activity against a variety of kinases (> 80 kinases) and was identified as an inhibitor of platelet-derived growth factor receptors (PDGFRα and PDGFRβ), vascular endothelial growth factor receptors (VEGFR1, VEGFR2, and VEGFR3), stem cell factor receptor (KIT), Fms-like tyrosine kinase-3 (FLT3), colony stimulating factor receptor Type 1 (CSF-1R), and the glial cell-line derived neurotrophic factor receptor (RET). sunitinib inhibition of the activity of these RTKs has been demonstrated in biochemical and cellular assays, and inhibition of function has

been demonstrated in cell proliferation assays. The primary metabolite exhibits similar potency compared to sunitinib in biochemical and cellular assays.

Sunitinib inhibited the phosphorylation of multiple RTKs (PDGFRβ, VEGFR2, KIT) in tumor xenografts expressing RTK targets *in vivo* and demonstrated inhibition of tumor growth or tumor regression and/or inhibited metastases in some experimental models of cancer. sunitinib demonstrated the ability to inhibit growth of tumor cells expressing dysregulated target RTKs (PDGFR, RET, or KIT) *in vitro* and to inhibit PDGFRβ-and VEGFR2-dependent tumor angiogenesis *in vivo*.

DOSE FORM AND STRENGTH

Capsules: 12.5 mg, 25 mg, 37.5 mg, 50 mg sunitinib.

DOSE & ADMINISTRATION

GIST and Advanced RCC:

- The recommended dosage is 50 mg orally once daily for the first 4 weeks of each 6-week cycle (Schedule 4/2).

Adjuvant Treatment of RCC:

- The recommended dosage is 50 mg orally once daily for the first 4 weeks of a 6-week cycle (Schedule 4/2) for a maximum of 9 cycles.

pNET:

- The recommended dosage is 37.5 mg orally once daily.