FIRST TIME GENERIC APPROVAL

Brand Name	Nexavar®
Generic Name	sorafenib tosylate
Drug Manufacturer	Mylan Pharmaceuticals Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

September 10, 2020

LAUNCH DATE

June 1, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 207012

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Sorafenib tablets are a kinase inhibitor indicated for the treatment of:

- Unresectable hepatocellular carcinoma
- Advanced renal cell carcinoma
- Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) refractory to radioactive iodine treatment.

MECHANISMS OF ACTION

Sorafenib is a kinase inhibitor that decreases tumor cell proliferation *in vitro*. Sorafenib was shown to inhibit multiple intracellular (c-CRAF, BRAF and mutant BRAF) and cell surface kinases (KIT, FLT-3, RET, RET/PTC, VEGFR-1, VEGFR-2, VEGFR-3, and PDGFR-ß). Several of these kinases are thought to be involved in tumor cell signaling, angiogenesis and apoptosis. Sorafenib inhibited tumor growth of HCC, RCC, and DTC human tumor xenografts in immunocompromised mice. Reductions in tumor angiogenesis were seen in models of HCC and RCC upon sorafenib treatment and increases in tumor apoptosis were observed in models of HCC, RCC, and DTC.

DOSE FORM AND STRENGTH

Tablets: 200 mg

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DOSE & ADMINISTRATION

The recommended dosage is 400 mg orally twice daily without food.