Nexanib (Sorafenib) Innerleaf design (English)

Pantone Metallic Coated 8483 C L - 195 mm X W - 255 mm

Nexanib™
Sorafenib

Jenphar Bangladesh | جنفار بنغلاديش

Composition:
Nexanib Tablet: Each film coated tablet contains Sorafenib Tosylate INN equivalent to Sorafenib 200 mg.

Pharmacology:
Sorafenib is a kinase inhibitor that decreases tumor cell proliferation. 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. 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.

Indications:
Sorafenib is a kinase inhibitor indicated for the treatment of

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

Dose and administration:
The recommended daily dose of Sorafenib is 400 mg (2 x 200 mg tablets) taken twice daily without food (at least 1 hour before or 2 hours after a meal).

Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs.

Contra-indications:
Sorafenib is contraindicated in patients with known severe hypersensitivity to Sorafenib or any other component of Nexanib. Sorafenib in combination with carboplatin and paclitaxel is contraindicated in patients with squamous cell lung cancer.

Warning and Precautions:
Cardiovascular Events: Consider temporary or permanent discontinuation of Sorafenib.

Bleeding: Discontinue Sorafenib if needed.

Hypertension: Monitor blood pressure weekly during the first 6 weeks and periodically thereafter.

Dermatologic Toxicities: Interrupt and/or decrease dose. Discontinue for severe or persistent reactions, or if Stevens-Johnson syndrome and toxic epidermal necrolysis is suspected.

Gastrointestinal Perforation: Discontinue Sorafenib.

QT Prolongation: Monitor electrocardiograms and electrolytes inpatients at increased risk for ventricular arrhythmias.

Drug-Induced Liver Injury: Monitor liver function tests regularly; discontinue for unexplained transaminase elevations.

Embryo-Fetal Toxicity: Sorafenib may cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Impairment of TSH suppression in DTC: Monitor TSH monthly and adjust thyroid replacement therapy in patients with thyroid cancer.

Adverse Effects:
The most common adverse effects (≥20%) for Sorafenib are diarrhea, fatigue, infection, alopecia, hand-foot skin reaction, rash, weight loss, decreased appetite, nausea, gastrointestinal and abdominal pains, hypertension, and hemorrhage.

Use in specific populations:
Pregnancy: There are no available data in pregnant women to inform a drug associated risk.

Lactation: There are no data on the presence of Sorafenib or its metabolites in human milk, or its effects on the breast-fed child or on milk production.

Females and Males of Reproductive Potential:
Females: Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Sorafenib.

Males: Advise male patients with female partners of reproductive potential and pregnant partners to use effective contraception during treatment with Sorafenib and for 3 months after the last dose of Sorafenib.

Pediatric Use: The safety and effectiveness of Sorafenib in pediatric patients have not been studied.

Geriatric Use: No differences in safety or efficacy were observed between older and younger patients.

Patients with Hepatic Impairment: No dose adjustment is necessary for patients with mild or moderate hepatic impairment. The pharmacokinetics of sorafenib have not been studied in patients with severe (Child-Pugh C) hepatic impairment.

Patients with Renal Impairment: No dose adjustment is necessary for patients with mild, moderate or severe renal impairment who are not on dialysis. The pharmacokinetics of sorafenib have not been studied in patients who are on dialysis.

Drug Interactions:
Effect of Strong CYP3A4 Inducers: Avoid concomitant use of strong CYP3A4 inducers (such as, carbamazepine, dexamethasone, phenobarbital, phenytoin, rifampin, rifabutin, St. John's wort), when possible, because these drugs can decrease the systemic exposure to Sorafenib.

Effect of Strong CYP3A4 Inhibitors: Ketoconazole, a strong inhibitor of CYP3A4 and P-glycoprotein, administered at a dose of 400 mg once daily for 7 days did not alter the mean AUC of a single oral dose of Sorafenib.

Drugs that Increase Gastric pH: No dose adjustment for Sorafenib is necessary.

Overdose:
There is no specific treatment for Sorafenib overdose. The highest dose of Sorafenib studied clinically is 800 mg twice daily. In cases of suspected overdose, Sorafenib should be withheld and supportive care instituted.

Storage:
Keep in a cool and dry place below 25° C, protect from light. Keep out of the reach of children.

Packing:
Nexanib Tablet: Each box contains 8/28's film coated tablets and one packet silica gel in a sealed HDPE container.

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Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.