Sorasiba™

Sorafenib

COMPOSITION

Sorasiba™ Tablet: Each film coated tablet contains Sorafenib Tosylate INN equivalent to 200 mg of Sorafenib free base.

PHARMACOLOGY

Sorafenib is a kinase inhibitor that decreases tumor cell proliferation in vitro. Sorafenib was shown to inhibit multiple intracellular (CRAF, BRAF and mutant BRAF) and cell surface kinases (KIT, FLT-3, RET, VEGFR-1, VEGFR-2, VEGFR-3, and PDGFR-β). Several of these kinases are thought to be involved in tumor cell signaling, angiogenesis, and apoptosis. Sorafenib inhibited tumor growth and angiogenesis of human hepatocellular carcinoma and renal cell carcinoma and several other human tumor xenografts in immunocompromised mice.

INDICATION

Hepatocellular Carcinoma: **Sorasiba**™ is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC).
Renal Cell Carcinoma: **Sorasiba**™ is indicated for the treatment of patients with advanced renal cell carcinoma (RCC).
Differentiated Thyroid Carcinoma: **Sorasiba**™ is indicated for the treatment of patients with Differentiated Thyroid Carcinoma (DTC).

DOSAGE & ADMINISTRATION

The recommended daily dose of **Sorasiba**™ 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. It is recommended that Sorafenib should be administered without food or with a low or moderate fat meal. If the patient intends to have a high-fat meal, Sorafenib tablets should be taken at least 1 hour before or 2 hours after the meal. The tablets should be swallowed with a glass of water. Management of suspected adverse drug reactions may require temporary interruption and/or dose reduction of **Sorasiba**™. When dose reduction is necessary, the **Sorasiba**™ dose may be reduced to 400 mg once daily. If additional dose reduction is required, **Sorasiba**™ may be reduced to a single 400 mg dose every other day. Or, as directed by the registered physicians

SIDE EFFECTS

The most common side effects of this tablet are- Cardiac ischemia, Infarction, Hemorrhage, Hypertension, Hand-foot skin reaction, rash, Stevens-Johnson syndrome, Gastrointestinal perforation and Drug-Induced Hepatitis.

CONTRAINDICATIONS

Sorafenib is contraindicated in patients with known severe hypersensitivity to Sorafenib or any other component of Sorafenib. Sorafenib in combination with Carboplatin and Paclitaxel is contraindicated in patients with squamous cell lung cancer.

USE IN PREGNANCY & LACTATION

Sorafenib should not be used during pregnancy. It is not known whether Sorafenib is excreted in human milk.

DRUG INTERACTIONS

CYP3A4 inducers: Can increase the metabolism of Sorafenib and decrease the AUC of Sorafenib. Caution is recommended when Sorafenib is coadministered with Docetaxel. Co-administration of Neomycin or other antibiotics that cause major ecological disturbances of the gastrointestinal microflora may lead to a decrease in Sorafenib bioavailability. Higher mortality has been reported in patients with squamous cell carcinoma of the lung treated with Sorafenib in combination with platinum-based chemotherapies.

PRECAUTIONS

• Cardiac ischemia and/or infarction may occur. Consider temporary or permanent discontinuation of Sorafenib. • Bleeding may occur. If bleeding necessitates medical intervention, consider discontinuation of Sorafenib. • Hypertension usually occurred early in the course of treatment and was managed with antihypertensive therapy. Monitor blood pressure weekly during the first 6 weeks and periodically thereafter and treat as required. • Hand-foot skin reaction and rash are common. Management may include topical therapies for symptomatic relief, temporary treatment interruption and/or dose modification or in severe or persistent cases, permanent discontinuation. • Gastrointestinal perforation is an uncommon adverse reaction. In the event of a gastrointestinal perforation, Sorafenib should be discontinued. • Temporary interruption of Sorafenib is recommended in patients undergoing major surgical procedures. • QT Prolongation: Monitor for prolonged QT intervals in patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, and electrolyte abnormalities. Avoid in patients with congenital long QT syndrome.

USE IN SPECIAL POPULATION

Renal Function Impairment: No dose adjustments are necessary for mild, moderate or severe renal function impairment in patients not undergoing dialysis.
Hepatic Function Impairment: Mild (Child-Pugh class A) and moderate (Child-Pugh class B) hepatic function impairment decreased AUC by 23% and 65% respectively. Not studied in severe (Child-Pugh class C) hepatic function impairment.

OVERDOSE

There is no specific treatment for Sorafenib overdose. The highest dose of Sorafenib studied clinically is 800 mg twice daily. The adverse reactions observed at this dose were primarily diarrhea and dermatologic. In cases of suspected overdose, Sorafenib should be withheld and supportive care instituted.

STORAGE

Keep away from light & moisture, store in cool & dry place. Store below 30°C. Keep out of the reach of children.

HOW SUPPLIED

Sorasiba™ Tablet: Each box contains 12 tablets in Alu-Alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH