For the treatment of unresectable hepatocellular carcinoma (uHCC)

Nexavar® (sorafenib) tablets

Stivarga® (regorafenib) tablets

Optimize every step toward extended overall survival (OS) with a uHCC treatment plan[1,2,3]

References: 1. NEXAVAR Prescribing Information. **2.** STIVARGA Prescribing Information. **3.** Bruix J, Qin S, Merle P, *et al*; on behalf of the RESORCE Investigators. Regorafenib for patients with hepatocellular carcinoma who progressed on sorafenib treatment (RESORCE): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet.* 2017;389(10064):56-66.

Study design: Randomized, double-blind, parallel-group, (379 to regorafenib and 194 to placebo) phase 3 trial in adults with HCC who tolerated sorafenib (≥400 mg/day for ≥20 of last 28 days of treatment), progressed on sorafenib. Participants were randomly and stratified to best supportive care plus oral regorafenib 160 mg or placebo once daily during weeks 1–3 of each 4-week cycle. The primary endpoint was overall survival (defined as time from randomization to death due to any cause).

Findings: Regorafenib improved overall survival with a hazard ratio of 0.63 (95% CI 0.50–0.79; one-sided p<0.0001); median survival was 10.6 months (95% CI 9.1–12.1) for regorafenib versus 7.8 months (6.3–8.8) for placebo.

NEXAVAR (1C 60/50(N)) Prescribing Information

Dosage and administration: The recommended daily dose of sorafenib is 400 mg (2 x 200 mg tablets) taken twice a day, either without food or together with a low fat or moderate fat meal. Treatment should be continued until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. **Indication:** Treatment of patients with hepatocellular carcinoma (HCC) who are unable to undergo surgery and in whom local chemotherapy is unsuitable. Treatment of patients with locally advanced or metastatic differentiated thyroid carcinoma refractory to radioactive iodine. Treatment of patients with advanced renal cell carcinoma. **Contraindication:** Patients with known severe hypersensitivity to sorafenib or any of the excipients. **Warnings and precautions:** Pregnancy; Women should avoid becoming pregnant while on therapy. Dermatological Toxicities; Hand-foot skin reaction and rash represent the most common adverse drug reactions, management of dermatologic toxicities may include topical therapies for symptomatic relief, temporary treatment interruption and/or dose modification of sorafenib. Hypertension; Usually mild to moderate, occurred early in the course of treatment, and was amenable to management with standard antihypertensive therapy. **Drug - Drug interactions:** UGT1A pathway; Caution is recommended when administering sorafenib together with compounds that are metabolized/eliminated predominantly by the UGT1A1 pathway. Docetaxel; Concomitant use of docetaxel with sorafenib, resulted in a 36-80% increase in docetaxel AUC. Neomycin; Co-administration of neomycin may cause a decrease in sorafenib bioavailability. **Others drug-related adverse events:** Diarrhea, fatigue, alopecia, infection, hand - foot skin reaction, rash. **Patients with hepatic impairment:** No data is available on patients with Child Pugh C (severe) hepatic impairment. Since sorafenib is mainly eliminated via the hepatic route, exposure might be increased in patients with severe hepatic impairment. **Shelf-life:** 3 years, do not store above 30°C.

STIVARGA (1C 136/56(N)) Prescribing Information

Dosage and administration: The recommended dose is 160 mg regorafenib (4 x 40 mg tablets), taken orally once daily for 3 weeks on therapy at the same time each day after a light meal followed by 1 week off therapy to comprise a cycle of 4 weeks. Treatment should continue as long as benefit is observed or until unacceptable toxicity occurs. **Indication:** Treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, fluoropyrimidine-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy. Treatment of patients with gastrointestinal stromal tumors (GIST) who have been previously treated with 2 tyrosine kinase inhibitors. Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. **Contraindications:** There is no contraindication to the use of STIVARGA. **Warnings and precautions:** Severe liver function test abnormalities (Grade 3 to 4) and hepatic dysfunction with clinical manifestations (including fatal outcomes) have been reported in a small proportion of patients. An increased incidence of hemorrhagic events, myocardial ischemia and infraction, as well as arterial hypertension may occur following STIVARGA administration. Reversible Posterior Leukoencephalopathy Syndrome (RPLS), gastrointestinal perforation, and fistulae have been reported in association with STIVARGA treatment. Temporary interruption of STIVARGA therapy is recommended in patients undergoing major surgical procedures. **Drug - Drug interactions:** Inhibitors/Inducers of CYP3A4; It is recommended to avoid concomitant use of strong inhibitors of CYP3A4 activity as their influence on the steady-state exposure of regorafenib and its metabolites (M-2 and M-5) has not been studied and strong CYP3A4 inducers may also increase metabolism of regorafenib, strong inducers of CYP3A4 should be avoided. UGT1A1 and UGT1A9 substrates; Co-administration of regorafenib may increase systemic exposure to UGT1A1 and UGT1A9 substrates. The clinical significance of these findings is unknown. **Others drug-related adverse events:** Asthenia/fatigue, hand-foot skin reaction, diarrhea, decreased appetite and food intake, hypertension, dysphonia and infection. **Patients with hepatic impairment:** No dose adjustment is required in patients with mild hepatic impairment. **Patients with renal impairment:** No dose adjustment is required in patients with mild or moderate renal impairment. **Shelf-life:** 3 years, do not store above 30°C. Keep the bottle tightly closed after first opening. Once the bottle is opened the medicinal product has shown to be stable for 7 weeks even without the desiccant. Thereafter, the medicinal product is to be discarded.

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โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารอ้างอิงฉบับสมบูรณ์และเอกสารกำกับยา
ใบอนุญาตโฆษณาเลขที่ ฆศ. 1311/2563