

Prescribing Information Update for SUTENT[®] (sunitinib malate)

July 12, 2010

Dear Health Care Provider:

Pfizer Oncology is committed to providing you with up-to-date information about SUTENT[®] (sunitinib malate) capsules. This letter is to inform you of an important update to the SUTENT prescribing information (PI). The following boxed warning and safety information has been added to the PI for SUTENT:

WARNING: HEPATOTOXICITY

Hepatotoxicity has been observed in clinical trials and post-marketing experience. This hepatotoxicity may be severe and deaths have been reported.

WARNINGS and PRECAUTIONS

Hepatotoxicity

SUTENT has been associated with hepatotoxicity, which may result in liver failure or death. Liver failure has been observed in clinical trials (7/2281 [0.3%]) and post-marketing experience. Liver failure signs include jaundice, elevated transaminases and/or hyperbilirubinemia in conjunction with encephalopathy, coagulopathy, and/or renal failure. Monitor liver function tests (ALT, AST, bilirubin) before initiation of treatment, during each cycle of treatment, and as clinically indicated. SUTENT should be interrupted for Grade 3 or 4 drug-related hepatic adverse events and discontinued if there is no resolution. Do not restart SUTENT if patients subsequently experience severe changes in liver function tests or have other signs and symptoms of liver failure.

Safety in patients with ALT or AST $>2.5 \times$ ULN or, if due to liver metastases, $>5.0 \times$ ULN has not been established.

In addition, the labeling includes a new Medication Guide that your patients will receive when SUTENT is dispensed.

Pfizer maintains a global safety database, monitoring all clinical trials and reports of spontaneous adverse events. The incidence of liver failure referenced above is consistent with the very low rate of hepatic failure described in the clinical trials of sunitinib used to support original FDA registration in 2006. More than 91,000 patients worldwide have been treated with SUTENT.

SUTENT is approved for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate and for the treatment of advanced renal cell carcinoma (RCC). The approved dosing schedule is 50 mg daily with or without food, 4 weeks on treatment followed by 2 weeks off treatment. Dosing adjustments of 12.5 mg are recommended based on individual safety and tolerability.

The benefit/risk profile of SUTENT, established through large randomized clinical trials evaluating its safety and efficacy in patients with advanced RCC and as 2nd-line therapy for patients with GIST, remains favorable. SUTENT has played an important role in reshaping the treatment landscape for these 2 difficult-to-treat cancers.

We encourage you to take into account this updated labeling as described above when assessing the benefit/risk profile of SUTENT for your individual patients. **It is important to monitor liver function tests before initiation of treatment, during each cycle of treatment, and as clinically indicated.** We have enclosed the revised SUTENT prescribing information for your review. Should you have any questions regarding this update or the use of SUTENT, please call the Pfizer Medical Information Department at 1-800-438-1985.

Sincerely,



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