



Indications

Nexavar is indicated for the treatment of patients with advanced renal cell carcinoma.

Important Safety Considerations

- Nexavar in combination with carboplatin and paclitaxel is contraindicated in patients with squamous cell lung cancer
- Nexavar may cause fetal harm when administered to a pregnant woman. Women of childbearing potential are advised to avoid becoming pregnant and female patients should also be advised against breastfeeding while receiving Nexavar
- Cardiac ischemia and/or myocardial infarction may occur. Temporary or permanent discontinuation of Nexavar should be considered in patients who develop cardiac ischemia and/or myocardial infarction
- Gastrointestinal perforation was an uncommon adverse reaction and has been reported in less than 1% of patients taking Nexavar
- Uncommon but serious adverse reactions, including keratoacanthomas/squamous cell cancer of the skin and Stevens-Johnson Syndrome, have been reported in clinical trials
- An increased risk of bleeding may occur following Nexavar administration. If bleeding necessitates medical intervention, consider discontinuation of Nexavar
- Hypertension may occur early in the course of treatment. Monitor blood pressure weekly during the first 6 weeks and periodically thereafter and treat, as required
- Hand-foot skin reaction and rash are common and management may include topical therapies for symptomatic relief. In cases of any severe or persistent adverse reactions, temporary treatment interruption, dose modification, or permanent discontinuation of Nexavar should be considered. Temporary interruption of Nexavar therapy is recommended in patients undergoing major surgical procedures
- Nexavar can prolong the QT/QTc interval and increase the risk for ventricular arrhythmias. Avoid use in patients with congenital long QT syndrome and monitor patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, and electrolyte abnormalities
- Elevations in serum lipase and reductions in serum phosphate of unknown etiology have been associated with Nexavar. Monitor patients taking concomitant warfarin regularly for changes in prothrombin time, INR, or clinical bleeding episodes. Avoid concomitant use of strong CYP3A4 inducers, when possible, because inducers can decrease the systemic exposure of sorafenib. Nexavar exposure decreases when co-administered with oral neomycin. Effects of other antibiotics on Nexavar pharmacokinetics have not been studied
- Most common adverse reactions reported for Nexavar-treated patients vs placebo-treated patients in advanced RCC, respectively, were: diarrhea (43% vs 13%), rash/desquamation



(40% vs 16%), fatigue (37% vs 28%), hand-foot skin reaction (30% vs 7%), alopecia (27% vs 3%), and nausea (23% vs 19%). Grade 3/4 adverse reactions were 38% vs 28%

- During postapproval use of Nexavar, the following adverse drug reactions have been identified: angioedema and drug-induced hepatitis, including reports of hepatic failure and death



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