Generic Name:
Cabozantinib
Trade Name:
Cabometyx
Company:
Exelixis
Notes:

Exelixis announcedFDA approval of a new indication for cabozantinib in patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

Approval was based on results from the CELESTIAL Phase III pivotal trial that enrolled patients with advanced HCC who received prior sorafenib. Cabozantinib demonstrated a statistically significant and clinically meaningful improvement in overall survival versus placebo.

The tablets come in 20-, 40-, and 60-mg dosage strengths. The recommended dose is 60 mg orally, once daily. The drug should be administered at least 1 hour before or at least 2 hours after eating. Tablets should not be substituted with cabozantinib capsules.

The most common adverse events are palmar-plantar erythrodysesthesia, hypertension, increased aspartate aminotransferase, fatigue, and diarrhea. Serious adverse effects include hemorrhage, perforation of the stomach or intestinal or fistula; and blood clots, stroke, heart attack, and chest pain.

Medication Monitor Categories:
Supplemental Approvals