



*XELODA® (capecitabine) is indicated as a single agent for adjuvant treatment in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred. XELODA was non-inferior to 5-fluorouracil and leucovorin (5-FU/LV) for disease-free survival (DFS). Although neither XELODA nor combination chemotherapy prolongs overall survival (OS), combination chemotherapy has been demonstrated to improve disease-free survival compared to 5-FU/LV. Physicians should consider these results when prescribing single-agent XELODA in the adjuvant treatment of Dukes' C colon cancer.

WARNING: For patients receiving XELODA and warfarin concomitantly, frequent monitoring of INR or prothrombin time (PT) is recommended. A clinically important drug interaction between XELODA and warfarin has been demonstrated. Altered coagulation parameters and/or bleeding and death have been reported. Clinically significant increases in PT and INR have been observed within days to months after starting XELODA, and infrequently within one month of stopping XELODA. These events occurred in patients with and without liver metastases. Age greater than 60 and a diagnosis of cancer independently predispose patients to an increased risk of coagulopathy.

Contraindications and Warnings: XELODA is contraindicated in patients who have a known hypersensitivity to capecitabine or to any of its components or to 5-fluorouracil. XELODA is contraindicated in patients with known dihydropyrimidine dehydrogenase (DPD) deficiency.