Generic Name:
Mesalamine
Trade Name:
Lialda
Company:
Shire
Notes:

Shire announced that mesalamine delayed-release tablets (Lialda) have been FDA approved for the maintenance of remission in patients with ulcerative colitis. The tablets were originally approved in 2007 for the induction of remission in patients with active, mild to moderate ulcerative colitis. Approval was based on data from a double-blind, multicenter study involving 826 adult patients in remission from ulcerative colitis. Patients were randomized to either Lialda 2.4 g/d or a comparator mesalamine delayed-release product , given as 1.6 g/d, with both groups having similar remission rates at Month 6 (83.7% and 81.5%, respectively). The most common adverse reactions with Lialda when used as maintenance therapy were ulcerative colitis, headache, abnormal liver function test, and abdominal pain
Medication Monitor Categories:
Supplemental Approvals
Use:

Management of patients with ulcerative colitis