INDICATION

Lialda® (mesalamine) is a prescription medication approved for the induction of remission in patients with active, mild to moderate ulcerative colitis (UC) and for the maintenance of remission of UC.

IMPORTANT SAFETY INFORMATION

Do not take Lialda if you are allergic to:
• salicylates, such as aspirin, or medications that contain aspirin
• aminosalicylates
• mesalamine or any other ingredients in Lialda

Tell your doctor if you:
• have or have had kidney problems. Kidney problems have been reported with medications that contain mesalamine, such as Lialda. Your doctor may check to see how your kidneys are working before starting Lialda and periodically while taking Lialda.

Please see additional Important Safety Information on the next page and Full Prescribing Information at http://pi.shirecontent.com/PI/PDFs/Lialda_USA_ENG.pdf

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Tell your doctor if you:

- have symptoms including cramping, stomach ache, bloody diarrhea, fever, headache, and rash. Medications that contain mesalamine, such as Lialda, have been associated with a condition that may be hard to tell apart from a UC flare. Call your doctor right away if you have any of these symptoms. He or she may tell you to stop taking Lialda.

- are allergic to sulfasalazine, as you may also be allergic to Lialda or medications that contain mesalamine.

- have or have had heart-related allergic reactions, such as inflammation of the heart muscle (myocarditis) or the lining of the heart (pericarditis). These reactions have been seen in patients taking Lialda or medications that contain mesalamine. Your chance of having these types of reactions may increase when taking Lialda.

- have or have had liver problems. Problems with liver function have been reported in patients who have or have had liver problems and were taking medications that contain mesalamine, such as Lialda.

- have a stomach blockage. It may take longer for Lialda to start working.

- have or have had skin conditions such as dermatitis and eczema. Patients who have or have had skin conditions while taking Lialda reported more severe skin reactions when exposed to sun and ultraviolet light. Let the doctor know if you have increased sensitivity of the skin to sun and ultraviolet light.

The most common side effects reported in clinical studies of Lialda were:

- ulcerative colitis
- abnormal liver function test results
- headache
- stomach ache
- passing gas

In clinical studies of Lialda, inflammation of the pancreas also occurred. If this happens to you, your doctor may tell you to stop taking Lialda.

Other side effects may occur.

Before starting Lialda, tell your doctor about all medications you are taking, including:

- non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen. Taking these medications with Lialda may increase your chance of kidney problems.

- azathioprine and 6-mercaptopurine. Taking these medications with Lialda may increase your chance of blood disorders.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.