

Composition : Mesalamine USP 400mg Tablet.

Indications : Mesalamine delayed-release tablet is indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis.

Dosage and administration : For the treatment of mildly to moderately active ulcerative colitis: For Adults : The usual dosage in adults is two 400-mg tablets to be taken three times daily with or without food (for a total daily dose of 2.4 grams), for a duration of 6 weeks. **For the maintenance of remission of ulcerative colitis:** The recommended dosage in adults is 1.6 grams daily, in divided doses. Or, as directed by the registered physician.

Side effects : Adverse reactions leading to withdrawal from Mesalamine delayed-release tablets included : diarrhea and colitis flare, dizziness, nausea, joint pain, and headache, rash, lethargy and constipation, dry mouth, malaise, mild indigestion and cramping, vomiting, muscle cramps and fever.

Contraindication : Mesalamine delayed-release tablet is contraindicated in patients with hypersensitivity to salicylates or to any of the components of the mesalamine delayed-release tablet.

Precaution : Caution should be exercised when using mesalamine or its metabolites in patients with known renal dysfunction or history of renal disease. It is recommended that all patients have an evaluation of renal function prior to

Canasa Tablet

initiation of mesalamine delayed-release tablets and periodically while on mesalamine delayed-release tablets therapy. Caution should be exercised when administering mesalamine delayed-release tablets to patients with liver disease.

Drug Interactions : Nephrotoxic Agents including NSAIDs: Renal reactions have been reported. Azathioprine or 6-mercaptopurine: Blood disorders have been reported.

Use in Pregnancy and lactation : Pregnancy category "C". There are no adequate & well controlled studies in pregnant women. Mesalamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Mesalamine & its N-acetyl metabolite are excreted into human milk. Caution should be exercised when Mesalamine is administered to nursing women.

Packing : Each box contains 3 x 10's tablets in blister pack.