



Mesala 400 (Mesalazine) is an orally administered delayed release tablet. Mesalazine diminishes inflammatory bowel disease by blocking cyclooxygenase and inhibiting prostaglandin synthesis in the colon.

COMPOSITION

Each delayed release tablet contains Mesalazine BP 400 mg.

INDICATION

Mesala 400 tablet is indicated for the treatment of inflammatory bowel diseases like ulcerative colitis and Crohn's disease.

DOSAGE AND ADMINISTRATION

Treatment of mild to moderate Ulcerative Colitis:

Adult: Recommended dosage is 800 mg (two 400 mg tablets) three times daily for a duration of 6 weeks.

Child (5 years of age and older): Daily dosage of **Mesala 400** is as follows:

Body weight	Morning Dosage	Evening Dosage	Duration
17 – 33 Kg	Two 400 mg tablets	One 400 mg tablet	6 weeks
33 – 54 Kg	Three 400 mg tablets	Two 400 mg tablets	

Maintenance dosage for Ulcerative Colitis:

The recommended dosage in adult is 1.6 grams (four 400 mg tablets) daily in two to four divided doses.

Maintenance of remission of Crohn's disease:

Child (12-17 years): 400-800 mg 2-3 times a day

Adult: 1.2 - 2.4 g daily in divided doses

SIDE EFFECT

The most common side effects are eructation, abdominal pain, constipation, dizziness, rhinitis, back pain and rash. Nasopharyngitis, headache, abdominal pain, dizziness, sinusitis, rash, cough and diarrhea are observed in children.

PRECAUTION

Evaluate the risk and benefits in patients with known renal and hepatic impairment during treatment.

Monitoring is required in Mesalazine-induced Acute Intolerance Syndrome. Discontinue Mesalazine if this type of syndrome is suspected.

CONTRAINDICATION

Mesalazine is contraindicated in patients with known hypersensitivity to the active ingredient or any other components of the formulation.

DRUG INTERACTION

Nephrotoxic agents i.e. NSAIDs: increases risk of nephrotoxicity; So, monitoring is required.
Azathioprine or 6-Mercaptopurine: Increases risk of blood disorders; monitoring of complete blood cell counts and platelet counts is required.

USE IN PREGNANCY AND LACTATION

There are no adequate and well controlled studies in pregnant women and lactating mother therefore, it should be given in pregnancy and lactation only if the potential benefit justifies the potential risk to the fetus or children.

USE IN GERIATRIC PATIENTS

May increase the risk of blood dyscrasias. Monitoring of complete blood cell counts and platelet counts is required.

STORAGE CONDITION

Keep in a cool & dry place (below 30° C), protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 50 tablets in Alu-Alu blister pack.