

BYE BYE INFLAMMATION



MESAHENZ

Mesalamine 400 mg & 800 mg Delayed Release and
1200 mg Prolonged Release Tablets

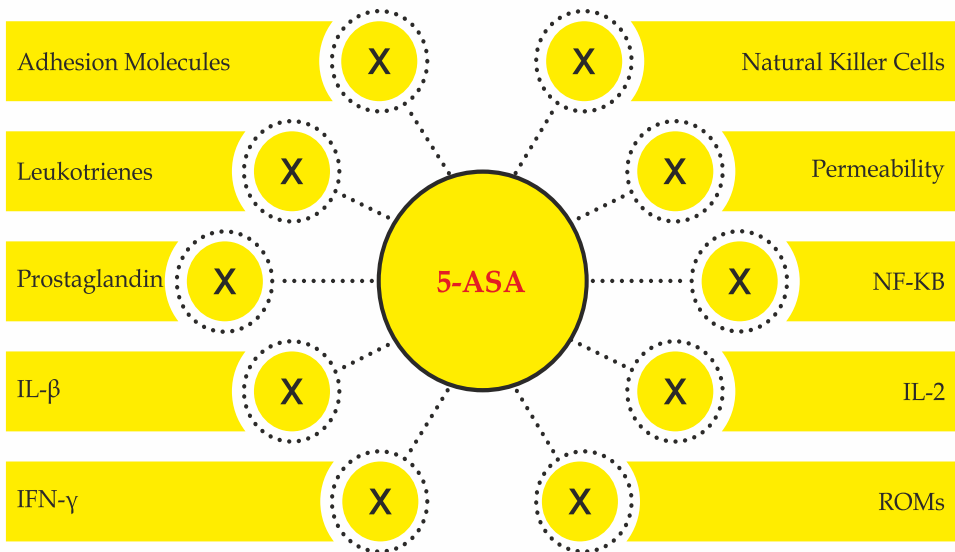
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Background:

- ✓ As per ISG, 64.4% of IBD patient suffers from Ulcerative Colitis & 25.3% suffers from Crohn's disease.¹
- ✓ 5-aminosalicylic acid (5-ASA) preparations (eg, mesalamine) are well-established preparations used in the management of inflammatory bowel disease.²
- ✓ Mesalamine and its derivatives are recommended as first line therapy for UC, on basis of favorable efficacy and safety profiles.³
- ✓ Mesalamine is useful in controlling active inflammation, maintaining remission and for chemoprevention.³

Mechanism of Mesalamine⁴:



- ✓ The action of 5-ASA is predominantly topical at the site of inflammation.
- ✓ The mechanisms of action of 5-ASA are numerous and not entirely understood. It has a potent inhibitory effect on a number of pro-inflammatory mediators released by the mucosa, including Roms, Leukotrienes, Interleukin 1 and Tumor Necrosis Factor alpha (TNF α).

Clinical Evidence:

Sr. no	Study	Design	Subjects	Outcomes
1	Am J Gastroenterol;2005	RCT	The study conducted with delayed-release oral mesalamine at 4.8 g/day (800 mg tablet) for the treatment of moderately active 86 ulcerative colitis patients.	Patients with moderately active ulcerative colitis treated with 4.8 g/day of mesalamine (800 mg tablet) are significantly more likely to achieve overall improvement at 6 week compared to patients treated with 2.4 g/day .
2	Gastroenterology; 138:1286-1296'2010	RCT	To study the efficacy and safety of once-daily dosing of delayed release mesalamine compared with twice-daily dosing for maintaining remission in 1023 UC patients .	Once-daily dosing of delayed-release mesalamine at doses of 1.6 -2.4 g/day was shown to be as effective as twice-daily dosing for maintenance of clinical remission in patients with UC .
3	Journal of Crohn's and Colitis, 2016	RCT	To study assessed the efficacy of maintenance treatment with mesalamine following achievement of complete or partial remission after induction treatment with high-dose mesalamine on 717 patients .	Once-daily dosing of delayed-release mesalamine at doses of 2.4 g to 4.8 g/day was as effective as twice-daily dosing for maintenance of clinical remission in patients with UC .

Why Mesahenz?

- ✓ Oral prolonged-release mesalamine in Mesahenz is effective for maintenance and induction of remission of mild to moderately active colitis, both in patients with distal disease and in those with pancolitis.²
- ✓ Oral delayed-release mesalamine in Mesahenz is effective in active or quiescent ulcerative colitis as well in active and quiescent Crohn's disease.⁴
- ✓ Delayed release mesalamine 4.8 g/day (800mg tablet) is efficacious and well tolerated in patients with moderately active UC.⁵
- ✓ Prolonged-release mesalamine appears to be effective in the treatment of Crohn's disease.⁶
- ✓ Mesalamine given alone or in combination with probiotics appear to be better for maintaining remission of symptomatic uncomplicated diverticular disease.⁷

Reference:

1. Indian J Gastroenterol;31(6): 299-306;2012
2. Therapeutics and Clinical Risk Management; 3(5): 919-927; 2007
3. Can J Gastroenterol Vol 24(2);2010
4. Journal of Crohn's and Colitis;149-156'2009
5. Drugs;57(3): 383-408; 1999
6. Am J Gastroenterol;100(11):2478-85; 2005
7. Aliment Pharmacol Ther'38(7):741751;2013

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Description:

MESAHENZ for oral administration is a formulation of mesalamine, an amino salicylate anti-inflammatory agent for gastrointestinal use.

Indication:

Treats inflammatory bowel disease, such as

- ✓ Ulcerative colitis and mild-to-moderate Crohn's disease.
- ✓ Uncomplicated Diverticular Disease.

Clinical Pharmacology:

Sulfasalazine is split by bacterial action in the colon into sulfa pyridine and mesalamine. It is thought that the mesalamine component is therapeutically active in ulcerative colitis.

Mechanism of Action:

Mesalamine appears to be multi-factorial. 5-ASA (5-aminosalicylic acid) is thought to affect the inflammatory process through its ability to inhibit prostaglandin synthesis, interfere with leukotriene synthesis and consequent leukocyte migration as well as act as a potent scavenger of free radicals.

Dosage:

The recommended dosage for the induction of remission in adult patients with active, mild to moderate ulcerative colitis is two to four 1.2g tablets to be taken once daily with meal for a total daily dose of 2.4g or 4.8g. Treatment duration in controlled clinical trials was up to 8 weeks.

Presentation:

MESAHENZ is available as:

- ✓ Mesalamine Delayed Release 400 mg Tablets,
- ✓ Mesalamine Delayed Release 800 mg Tablets,
- ✓ Mesalamine Prolonged Release 1200 mg Tablets

Storage:

Store in cool and dry place. Protect from light and moisture.

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