

Apriso® (mesalamine) – First-time generic

- On November 27, 2019, Mylan launched an <u>AB-rated</u> generic version of Bausch Health <u>Apriso</u> (<u>mesalamine</u>) 375 mg extended-release capsules.
- Apriso is approved for the maintenance of remission of ulcerative colitis in patients 18 years of age and older.
- Mesalamine is also available as branded 250 mg and 500 mg controlled-release capsules
 (Pentasa®), generic 800 mg delayed-release tablets, brand (Lialda®) and generic 1,200 mg delayed-release tablets, brand (Delzicol®) and generic 400 mg delayed-release capsules, brand (Rowasa®) and generic rectal enema, and brand (Canasa®) and generic rectal suppository.
 - Pentasa is approved for the induction of remission and for the treatment of patients with mildly to moderately active ulcerative colitis.
 - Mesalamine 800 mg delayed-release tablets are approved for the treatment of moderately active ulcerative colitis in adults.
 - Mesalamine 1,200 mg delayed-release tablets are approved for the induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.
 - Mesalamine 400 mg delayed-release capsules are approved for the treatment of mildly to moderately active ulcerative colitis in patients 5 years of age and older, and for the maintenance of remission of ulcerative colitis in adults.
 - Mesalamine rectal enema and suppository are approved for the treatment of active mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis.



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