

Delzicol® (mesalamine) – First-time generic

- On May 10, 2019, <u>Teva launched</u> a generic version of Allergan's <u>Delzicol (mesalamine)</u> delayedrelease capsules.
- Delzicol is 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 is also available generically as a <u>delayed-release 1.2 gm tablet</u>, <u>delayed-release 800 mg tablet</u>, <u>rectal suspension enema</u>, and <u>rectal suppository</u>, and a brand extended-release capsule (<u>Apriso</u>), controlled-release capsule (<u>Pentasa</u>), and sulfite-free rectal suspension enema (<u>sfRowasa</u>).
 - The delayed-release 1.2 gm tablet is approved for the induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.
 - The delayed-release 800 mg tablet is approved for the treatment of moderately active ulcerative colitis in adults.
 - The enema and sfRowasa are approved for the treatment of active mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis.
 - The rectal suppository is approved in adults for the treatment of mildly to moderately active ulcerative proctitis.
 - Apriso is approved for the maintenance of remission of ulcerative colitis in patients 18 years of age and older.
 - Pentasa is approved for the induction of remission and for the treatment of patients with mildly to moderately active ulcerative colitis.
- According to IMS data as of February 2019, Delzicol had annual sales of approximately \$130 million in the U.S.



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