

Canasa® (mesalamine) - First-time generic

- On December 17, 2018, <u>Mylan launched</u> an <u>AB-rated</u> generic version of Allergan's <u>Canasa</u> (<u>mesalamine</u>) rectal suppositories.
 - Mylan has been granted 180-days of exclusivity.
- Canasa is approved for the treatment of mildly to moderately active ulcerative proctitis in adults.
- Mesalamine is also available generically as <u>delayed-release 800 mg tablets</u>, <u>delayed-release 1.2 gm tablets</u> and an <u>enema</u>, and as brand extended-release capsules (<u>Apriso</u>[®], <u>Pentasa</u>[®]) and delayed-release capsules (<u>Delzicol</u>[®]).
 - The 800 mg delayed-release tablets are indicated for the treatment of moderately active ulcerative colitis in adults.
 - The 1.2 gm delayed-release tablets are indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.
 - The enema is indicated for the treatment of active mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis.
 - Apriso is indicated for the maintenance of remission of ulcerative colitis in patients 18 years of age and older.
 - Pentasa is indicated for the induction of remission and for the treatment of patients with mildly to moderately active ulcerative colitis.
 - Delzicol is indicated 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.
- According to IQVIA[™], U.S. sales for Canasa were approximately \$263 million for the 12 months ending October 31, 2018.



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