

Pentasa® (mesalamine) - First-time generic

- On May 17, 2022, <u>Sun Pharma launched</u> an <u>AB-rated</u> generic version of Takeda's <u>Pentasa</u> (<u>mesalamine</u>) 500 mg extended-release capsules.
 - Sun Pharma was granted 180-days of Competitive Generic Therapy exclusivity for generic Pentasa.
 - In addition, Prasco will launch an authorized brand alternative of Pentasa shortly.
- Pentasa is approved for the induction of remission and for the treatment of adult patients with mildly to moderately active ulcerative colitis.
- Mesalamine is also available as a brand 250 mg extended-release capsule (Pentasa), generic delayed-release capsule, generic extended-release 0.375 gram capsule, generic enema, generic rectal suppository, and generic delayed-release tablet.
 - Mesalamine delayed-release capsule 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 extended-release 0.375 gram capsules is approved for the maintenance of remission of ulcerative colitis in adults.
 - Mesalamine enema is approved for the treatment of active mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis in adults.
 - Mesalamine rectal suppository is approved in adults for the treatment of mildly to moderately active ulcerative proctitis.
 - Mesalamine delayed-release tablet is approved for the induction and maintenance of remission in adult patients with mildly to moderately active ulcerative colitis.
- According IQVIA Health data, Pentasa 500 mg had annualized U.S. sales of approximately \$213 million for the 12 months ending March 2022.



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