

Tecfidera® (dimethyl fumarate) – First-time generic approval

- On August 19, 2020, Mylan launched an AB-rated generic version of Biogen's Tecfidera (dimethyl fumarate) delayed-release capsules.
- Tecfidera is approved for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Mylan's generic Tecfidera is the first oral dosage form to receive generic approval for MS.
- According to IQVIA, U.S. sales for Tecfidera for the 12 months ending June 30, 2020 were approximately \$3.79 billion.



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