

## Gilenya® (fingolimod) – First-time generic

- On September 22, 2022, Viatris launched an <u>AB-rated</u> generic version of Novartis' <u>Gilenya</u> (fingolimod) 0.5 mg capsules.
  - Several other manufacturers received FDA approval of AB-rated generic versions of Gilenya 0.5 mg capsule: <u>Accord</u>, <u>Dr. Reddy's</u>, <u>Glenmark</u>, <u>HEC</u>, <u>Hetero</u>, <u>Prinston</u>, and <u>Sun</u>. Launch plans are pending for these generics.
- Gilenya 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 patients 10 years of age and older.
- Gilenya is also available as a 0.25 mg capsule with the same indication as Gilenya 0.5 mg.



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