

Gilenya[®] (fingolimod) – First-time generic

- On September 22, 2022, Viatris launched an [AB-rated](#) generic version of Novartis' [Gilenya \(fingolimod\)](#) 0.5 mg capsules.
 - Several other manufacturers received FDA approval of AB-rated generic versions of Gilenya 0.5 mg capsule: [Accord](#), [Dr. Reddy's](#), [Glenmark](#), [HEC](#), [Hetero](#), [Prinston](#), and [Sun](#). 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.